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Rules and Regulations

Federal Register
Vol. 56, No. 140
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DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

7 CFR Part 17

Regulations Governing the Financing of Commercial Sales of Agricultural Commodities

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Final rule.

SUMMARY: The Foreign Agricultural Service (FAS) is amending the regulations applicable to the financing of the sale and exportation of agricultural commodities pursuant to title I of the Agricultural Trade Development and Assistance Act of 1954, as amended (Pub. L. 480), to increase the initial freight payment due vessel owners from 90 percent to 95 percent and to require detention provisions in freight contracts to cover delays in loading due to the failure to open letters of credit in a timely manner when the Commodity Credit Corporation (CCC) finances any part of the ocean freight. The amendment also provides that vessel owners may collect the undisputed balance of freight in certain circumstances without the charterer's having signed the statement of facts and the laytime statement.

The purpose of these changes is to keep the costs of the Public Law 480, title I program as low as possible and insure that all persons desiring to participate in the shipping of commodities financed under Public Law 480, title I, receive fair and equitable treatment.

EFFECTIVE DATE: August 21, 1991. See **"SUPPLEMENTARY INFORMATION."**

FOR FURTHER INFORMATION CONTACT: Connie B. Delaplane, Director, P.L. 480 Operations Division, Export Credits, Foreign Agricultural Service, Room 4549 South Building, U.S. Department of Agriculture, 14th and Independence Avenue SW., Washington, DC 20250–1000. Telephone: (202) 447–3664.

SUPPLEMENTARY INFORMATION: The final rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512–1 and has been classified "nonmajor." It has been determined that this rule will not result in an annual effect on the economy of $100 million or more; will not cause a major increase in costs to consumers, individual industries, Federal, State or local government agencies or geographic regions; and will not have an adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign based enterprises in domestic or export markets.

It has been determined that the Regulatory Flexibility Act is not applicable to this proposed rule since CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with state and local officials. (See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 June 24, 1983).

Effective Date

The provisions of this amendment shall apply to arrangements for ocean transportation pursuant to ocean freight Invitations for Bids issued on or after August 21, 1991.

Background

On November 9, 1990, the Foreign Agricultural Service published a proposed rule (55 FR 47061) to amend the regulations governing the financing of the sale and exportation of agricultural commodities made available under Title I of the Agricultural Trade Development and Assistance Act of 1954, as amended (Pub. L. 480).

A number of comments were received supporting all or part of the proposed rule. Other comments are discussed below.

Discussion of Comments

Letter of Credit

Several comments objected to the requirement that importing countries open letters of credit (L/C's) for ocean freight before the vessel presents at the loading port whenever CCC finances any portion of the freight. The requirement was described as a hardship on importing countries, since the freight is not actually due until the vessel's arrival at the first discharge port.

It is important to note that this is not a new program requirement; it has been contained in each Title I agreement for a number of years. Requiring that ocean freight L/C's be opened before loading provides assurance of payment to vessel owners. Otherwise, they would have to load the commodity and sail without such security. Under existing regulations, suppliers of ocean transportation may load and sail without an L/C; however, they are not required to do so and they take such action at their own risk. See 7 CFR 17.6(g).

Other comments stated that freight should be due on loading to allow more competitive freight rates and to make Public Law 480 operate like commercial shipments. The program operated in this manner prior to 1960 at which time CCC found it necessary to change freight procedures to protect its interests. In 1959 an importing country fixed a vessel under a charter party to transport bagged rice. Before the vessel departed, and after receipt of freight payment on loading, the owner abandoned the vessel. CCC incurred additional freight charges and it was necessary to unload the cargo, fumigate and reload to another vessel. In order to protect both CCC and the importing country, the final rule retains the requirement for payment upon arrival at the first port of discharge.

Existing regulations already provide that, under certain circumstances (see § 17.14(l)), the supplier can collect the initial payment for ocean freight or ocean freight differential prior to the vessel's arrival at the first port of discharge. The supplier must first furnish CCC with an acceptable L/C from a U.S. bank so that the Controller can issue a waiver of the notice of arrival, a required payment document.

95 Percent Initial Freight Payment

Two comments questioned the study by the Maritime Administration, Department of Transportation, which showed that 10 percent was, in most

cases, more than the amount needed to cover despatch earned by the importing countries. FAS has reviewed a copy of the study and has also prepared a study of 155 shipments to 13 countries for the period 1986–1989, which confirmed the results of the study by the Maritime Administration. The FAS study showed only ten shipments (to six different countries) which resulted in despatch earnings in excess of 5 percent. Most of the countries in connection with which there have been such despatch earnings do not now participate in the Title I program or they have increased their contractual discharge rate since the time of the shipments covered by the studies. FAS will continue to review actual discharge rates in connection with shipments to Title I countries to insure that the contractual rates reflect current capabilities and are not set artificially low in order to guarantee or inflate despatch earnings.

Two comments stated that reducing the final freight payment to 5 percent may not leave importing countries enough funds to offset claims for cargo damage against the vessel operator or for leverage to insure that vessel owners pay carrying charges to commodity suppliers. However, the final freight payment was never intended to be used for such purposes; it was designed only to accommodate payment of despatch, if due. See 7 CFR 17.14(n).

Other comments asked about the procedure to be followed if despatch exceeds 5 percent. In the few instances where despatch exceeds 5 percent, both the importing country and CCC will be entitled to reimbursement from vessel owners upon request. CCC will use procedures already in place to address overfinancing for collection of CCC's portion of such ocean freight payment. Under § 17.17(a) of the regulations, claims for overpayment of ocean transportation must be settled by payment of dollars to CCC. CCC will then, in accordance with § 17.17(e), make an appropriate refund of local currency received or credit the participant's account.

Detention

A number of comments were received addressing the requirement that freight contracts must provide the vessel owner with the option of claiming detention if a vessel is delayed in loading because of the lack of an operable commodity or freight L/C.

Several comments noted that detention was not needed if the freight contract had a demurrage clause. They stated that demurrage was the conventional commercial remedy for delays to the vessel at load or discharge, while the remedies for late payment of freight were arbitration, liens on the cargo, and/or payment of interest on unpaid balances. However, allowing the supplier of ocean transportation to claim detention when loading is delayed because there is not an operable L/C emphasizes to importing countries the importance of promptly opening L/C's and places on the importing country the financial burden of such delay. Detention represents actual damages from the delay in loading the vessel and may be higher than the demurrage rate. Since the instances of delayed freight L/C's have been increasing, and freight rates would be expected to rise to recover the costs of such delay in payment, the final rule retains the requirement for detention provisions in order to reduce program costs to CCC.

Several comments expressed concern about excessively high detention rates; one comment suggested that the rule may encourage owners to claim the higher detention rate rather than agree to load the cargo or simply claim demurrage for L/C delays. However, there is a difference between demurrage and detention: The rate of demurrage is specified in advance in the contract, expressed as a daily rate. Demurrage is considered to be liquidated damages and the vessel owner may collect only the contractual demurrage rate for such delay, regardless of the actual cost of the delay to the owner. On the other hand, a "rate of detention" is not specified in the contract; damages for detention are unliquidated. Detention claims may be decided by arbitration or in court if the contracting parties cannot agree.

Therefore, freight offers under Invitations for Bids subject to this amendment should not contain a "detention rate". Such offers will not be considered non-responsive solely because a detention rate was given; however, the related charter parties and liner booking contracts may not contain a detention rate.

Two comments noted that suppliers of ocean transportation could simply raise their rates for demurrage and despatch if they desired to receive a more compensatory amount for delays of all kinds. Suppliers may, of course, do this at any time. However, the supplier would risk paying higher despatch, if despatch is earned, since it is a custom of the trade that the rates are tied—despatch is normally one-half the demurrage rate. This could lead to increased freight rates.

One comment stated that detention, in addition to demurrage, would penalize charterers twice. However, the regulation does not provide for both detention and demurrage for the same period of delay. Another comment asked that it be made clear that demurrage which is not in contention should be paid promptly by the chartèrer. This is the expectation. Section 17.14(n) currently states that the participant must make prompt payment of the undisputed balance due.

Two comments suggested that contracts provide for detention only if there is no freight L/C at the time of the vessel's arrival at the discharge port, when the freight is due. These comments do not acknowledge the unique nature of the title I program. The only assurance of payment the vessel owner has at the time of loading is an operable L/C. Another comment suggested that the vessel owner could refuse to discharge the commodity if the L/C were not available on arrival at the discharge port. This would not be a desirable option because the vessel could not undertake another voyage without disposing of the cargo on board; in addition, the vessel could be subject to legal action by the importing country once it arrived.

Three comments referred to the fact that factors beyond the control of the importing country may contribute to the late opening of L/C's and the country might then bear detention costs for such delay. Nevertheless, the most important element affecting the L/C is controlled by the importing country, which should begin the process immediately after commodities are purchased and vessels booked. If an importing country is aware of internal procedures or factors beyond its control which routinely slow the process, it should schedule commodity purchasing accordingly and allow sufficient lead time between awards and the beginning of the delivery period to insure that an operable L/C will be available. CCC will expedite its determination of ocean freight differential to assist importing countries in opening L/C's more quickly.

Another comment stated that it was not necessary to amend the regulations to require the contractual option of detention. However, adding this requirement to the regulations establishes the framework for detention claims and the mandatory nature of the requirement.

Finally, one comment stated that charterers should not have to pay detention "if all parties are agreeable to load the vessel." This is in keeping with the provisions of both the proposed and final rule. If the commodity supplier and the supplier of ocean transportation are willing to load without L/C's, there is no basis for a detention claim.

Calculating Detention

Several comments requested that clarification be provided on how detention should be calculated. The proposed rule stated that the period of detention would not begin earlier than the date the vessel presented its notice of readiness to load at the designated loading port within the contract laydays and would end when an acceptable letter of credit was established. Once begun, detention would continue only until the letter of credit was opened, or until the vessel began loading, whichever was earlier, regardless of subsequent delaying factors such as strikes or inclement weather.

One comment stated that detention should not apply if the vessel would have been unable to load even with an operable L/C. This is the intent of the regulation, which has been clarified by the insertion of the word "solely" in § 17.14(k)(7). This section now states that contracts must provide for detention for loading delays attributable solely to the decision of the supplier not to load because of the lack of an operable letter of credit. For example, if there is no letter of credit, but loading would have been impossible because of heavy rain, detention would not begin until loading was possible.

Two comments addressed the provision in the regulation which states that the period of detention shall end when an operable irrevocable letter of credit has been established. One comment asked who would pay in cases where a delay due to lack of an L/C caused additional delays—if, for example, the L/C was not opened until a time when conditions at the load port prohibited loading for several more days. The second comment stated that such additional delay should be considered detention. However, the intent of the regulation is that the period of detention be confined to the delay caused solely by the lack of an L/C. Delays occurring after the establishment of the operable L/C would be governed by the provisions in the charter party or booking note regarding laytime. The final rule has been revised to clarify that, if a supplier initially refused to commence loading but later agreed to load in advance of the establishment of the operable L/C, detention will end when the vessel begins loading.

One comment asked for clarification on the calculation of detention separate from reversible laydays. (For most title I shipments, laydays are reversible; that is, laytime is calculated at both load and discharge ports and demurrage/despatch is computed on the basis of total laytime saved.) The final rule states, as did the proposed rule, that time calculated as detention would not count as laytime. Detention could be claimed only for the time lost for delays due to lack of L/C. This means that laytime would be calculated in the usual manner on the period not covered by the detention claim.

Another comment asked if detention could be claimed by an owner if the notice of readiness were tendered before the beginning of the laydays. The regulation specifies that the period of detention shall not commence earlier than presentation of the vessel within the laydays specified in the charter party or booking contract and upon notification of the vessel's readiness to load. This is intended to prevent dentenion based on any period of time prior to the contract laydays.

One comment asked whether Saturday and Sunday would be included in the detention period. Since it is common for vessels to load on those days, and because detention is not bound by laytime provisions, Saturday and Sunday would be included, as well as holidays. The regulation has been revised to clarify this point.

A comment requested that the regulation itself make it clear that the L/C must be acceptable or operable. The proposed rule (§ 17.14(k)(7)) described it as an "operable irrevocable" L/C; the final rule adds the word "operable" to § 17.14(a)(4) for consistency. Several comments noted that there may be questions raised as to the definition of an "operable" L/C. However, just as in commercial transactions, any dispute in this regard must be resolved between the parties.

Another comment stated that the period of detention should not end until the owner views the L/C and can ascertain whether the L/C is operable. The rule was not changed to provide for this since it would not be advisable to discourage owners from taking an active role in informing themselves of the existence of the L/C and its contents. In addition, there should be only a slight delay between the time of establishing an L/C and its review by the owner.

Three comments stated that USDA should provide assistance in the collection of detention in order for it to be effective. In order to maintain a consistent approach to costs which are not financed by CCC, the final rule maintains the position that disputes regarding actual liability for detention and amounts due under a detention clause must be resolved between the parties to the contract. 7 CFR 17.6(d).

Another comment requested that the regulation require that detention be "paid" rather than "payable" when the vessel arrived at the first port of discharge. However, this change would not allow time for resolution of any difference of opinion as to the validity or the amount of the detention claim. The final rule retains the word "payable."

Laytime Statements and Statements of Fact

The proposed rule would have required that the freight L/C "contain" the provision in § 17.16(d)(iii) permitting acceptance of statements of facts and combined laytime statements under certain circumstances without signature by the charterer or consignee or their agents. The final rule retains the requirement that the charter party or booking note contain this provision. Since the freight L/C would clearly not be operable if it failed to reflect this regulatory and contractual requirement, the reference to the freight L/C has been deleted from § 17.14(k)(8). However, charterers are urged to review their L/C text carefully to insure compliance with this term. If the L/C is not operable, a claim for detention may result.

Several comments noted that, due to slow international mail delivery, the period of time allowed for charterers to review the laytime statement should be extended. The proposed rule allowed the supplier to receive payment based on laytime statements and statements of fact under certain circumstances if the charterer had not signed them 30 days after submission of the documents to the charterer.

The final rule addresses the fact that it is no longer necessary to rely on international mail to transmit documents. All of the countries which are expected to have title I programs in Fiscal Years 91 and 92 are served by commercial couriers at reasonable fees (less than $70 each way). The regulation has been amended to require the use of services such as commercial couriers or express mail for sending documents to the importing country whenever such services are available. In addition, facsimile transmission could also be used to transmit information to many countries for review before the documents themselves are forwarded.

One comment noted that charterers may be delayed in providing signed laytime statements because the suppliers do not submit them to the charterers promptly. The proposed rule stated that suppliers must certify that the documents were submitted to the charterer at least 30 days prior to the request for payment and that the charterer had been notified that

payment was being requested based on laytime statements and/or statements of fact signed only by the vessel master or owner. A false certification would subject the supplier to penalties for civil and criminal fraud. The final rule retains this requirement.

Another comment stated that it would be difficult for a country to recover despatch in case of a dispute over the statement of fact if payment had already been made. In such cases it is imperative that the country immediately advise the supplier in writing of any dispute amount of despatch (§ 17.18(d)(6)(iii)). The supplier must submit this written advice to the bank and may only collect the portion of the 5 percent balance which is not in dispute.

List of Subjects in 7 CFR Part 17

Agricultural commodities, Exports, Finance, Maritime carriers.

Accordingly, 7 CFR part 17, subpart A, is amended as follows:

1. The authority citation for part 17 is revised to read as follows:

Authority: (7 U.S.C. 1701–1705, 1736a, 1736c, 5676); E.O. 12220, 45 FR 44245.

2. In § 17.14, "90 percent" is changed to "95 percent" and "10 percent" is changed to "5 percent" in paragraphs (e)(3), (e)(4), (l)(8) and (n); and "90 percent" is changed to "95 percent" in paragraphs (l)(2), (l)(3), (l)(4), (l)(5)(ii), (l)(6), and (l)(7).

3. Section 17.14 is further amended by adding paragraph (a)(4), revising paragraphs (j) (9) and (10) and adding paragraphs (j)(11) and (k) (7) and (8), and amending paragraph (n) by adding a sentence at the end thereof, to read as follows:

§ 17.14 Ocean transportation.

(a) * * *

(4) When commodities are required to be transported in a U.S.-flag vessel, the government of the importing country must ensure that an operable irrevocable letter of credit has been opened in favor of the supplier of ocean transportation prior to the vessel's presentation for loading. The letter of credit shall provide for sight payment or acceptance of a draft, payable in U.S. dollars, for 100 percent of the ocean freight on the basis of the quantities and rates specified in the applicable charter party or liner booking contract.

* * * * *

(j) * * *

(9) Brokerage commissions in excess of 2½ percent of the freight;

(10) Any payments prohibited in § 17.8(c); and

(11) Detention.

(k) * * *

(7) Charter parties and liner booking contracts must specify that the participant shall be liable for detention of the vessel for loading delays attributable solely to the decision of the supplier of ocean transportation or the supplier of commodity not to commence loading because of the failure of the participant to establish an operable irrevocable ocean freight or commodity letter of credit. However, charter parties and liner booking contracts may not contain a specified detention rate. The ocean transportation supplier shall be entitled to reimbursement for detention costs for all time so lost, for each calendar day or any part of the calendar day, including Saturdays, Sundays and holidays. The period of such delay shall not commence earlier than upon presentation of the vessel at the designated loading port within the laydays specified in the charter party or booking contract, and upon notification of the vessel's readiness to load in accordance with the terms of the applicable charter party or booking contract. The period of such delay shall end at the time that operable irrevocable letters or credit have been established for commodity and ocean freight or the time the vessel begins loading, whichever is earlier. Time calculated as detention shall not count as laytime. Reimbursement for such detention shall be payable no later than upon the vessel's arrival at the first port of discharge.

(8) Charter parties and liner booking contracts which provide for dispatch earnings must contain the provision in § 17.18(d)(6)(iii) regarding acceptability under certain circumstances of statements of fact and combined laytime statements without signature by the charterer or consignee or their agents.

* * * * *

(n) * * * If the charterer does not agree with the dispatch computation, the charterer, consignee or their agent must immediately provide written notification to the supplier of ocean transportation and to CCC of the amount disputed and the reason for such dispute. (See § 17.18(d)(6)(iii).)

* * * * *

4. In § 17.18 paragraphs (d)(6) introductory text and (d)(6)(ii) are amended by changing "90 percent" to read "95 percent," and by revising paragraph (d)(6)(iii) to read as follows:

§ 17.18 Documentation.

* * * * *

(d) *Documents required for reimbursement of ocean freight financed separately from commodity price.* * * *

(6) * * *

(iii) A copy of the loading and discharging statements of facts and the combined laytime statement signed by the ship's master or owner and the charterer or consignee. Agents' signatures are acceptable. However, if 60 calendar days have elapsed since completion of discharge, as shown by the statement of fact, signature by the charterer or consignee or their agents is not required as long as the documents are accompanied by a statement signed by the supplier of ocean transportation certifying that the supplier submitted the statements of fact and combined laytime statement to the charterer for review (by means such as commercial courier or express mail, if available) at least 30 days prior to the request for payment and that the supplier has notified the charterer of the request for payment on this basis. If the charterer has advised the supplier in writing of any disputed amount of dispatch, a copy of this advice must be included in the request for payment and, in such case, only the portion of the 5% which is not in dispute is eligible for reimbursement.

* * * * *

Signed at Washington, DC, on July 3, 1991.

F. Paul Dickerson,

General Sales Manager, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 91–17385 Filed 7–19–91; 8:45 am]

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

[INS No. 1296–91]

RIN 1115–AB50

8 CFR Part 214

Nonimmigrant Classes; J–2 Employment Authorization

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule amends the regulations relating to employment authorization for the accompanying spouse and dependents of a J–1 exchange visitor by requiring the use of a standardized application form. The requirement that a J–2 spouse and dependent seeking employment authorization use a standardized application form will move the Service closer to the establishment of a uniform employment authorization document. The final rule will not only clarify the guidelines for adjudication, but bring the

J-2 employment regulation in line with the implementation regulations of the Immigration Reform and Control Act of 1986 (IRCA).

EFFECTIVE DATE: July 22, 1991.

FOR FURTHER INFORMATION CONTACT: Pearl B. Chang, Senior Immigration Examiner, Adjudications Division, Immigration and Naturalization Service, 425 I Street NW., room 7122, Washington, DC 20536, telephone (202) 514-3240.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 1991, the Immigration and Naturalization Service (Service) published a proposed rule with request for comments in the **Federal Register** at 56 FR 502-503 to amend the regulations relating to J-2 employment authorization. The purpose of the proposed rule was to establish guidelines for adjudication and to reflect the requirements imposed by the Immigration Reform and Control Act of 1986 (IRCA). The employer sanctions provisions of IRCA require that employers verify the identity and employment eligibility of persons they hire.

Title 8 of the Code of Federal Regulations, § 214.2(j) provides that the J-2 spouse and minor children of a J-1 exchange alien may accept employment with authorization by the Service. The current regulation permits a J-2 dependent to submit a request to the Service for employment authorization either orally or in writing. The Service usually approves such a request if it is evident that the employment is not for the support of the J-1 exchange alien. In the absence of a standardized procedure, each Service field office is left to set up its own procedural requirements, which has resulted in inconsistent decisions on requests for permission to work. This rule is intended not only to clarify the guidelines for adjudication, but also to bring the J-2 employment authorization process in line with the objective of standardizing employment authorization documents (EAD).

Discussion

Seven commentors responded to the proposed rule. All seven commentors requested that the Service rethink the proposal to require J-2 dependents to renew their employment authorization annually. They were concerned with the logistical burden this requirement would impose on the J-2 dependents, and urged the Service to maintain the current practice of granting J-2 dependents employment authorization for the duration of the authorized stay. Agreeing that the annual renewal requirement could be unduly burdensome to many J-2 dependents, the Service decided to stay with the existing procedure in the final rule. Since the average length of an exchange visitor program is less than four years, the Service will grant J-2 employment authorization for up to four years. The J-2 dependent might apply for renewal of employment authorization if the J-1 principal alien's program continues beyond the fourth year.

The commentors also expressed concern that the proposed rule did not provide for continued employment for J-2 dependents while the J-1 principal alien's application for extension of stay was pending. Two commentors requested that the Service change the current procedure to allow the concurrent filing of the J-1 principal alien's application for extension of stay and the J-2 dependent's application for employment authorization at the local Service office. Upon approval of the principal alien's extension of stay, the J-2 dependents could be issued an EAD. The Service did not adopt this suggestion because the EAD-issuance facilities at the district offices are equipped to handle only employment-authorization related adjudications. The EAD staff does not have access to the records necessary for extension of stay adjudications.

Three commentors stated that J-2 dependents should be allowed to continue employment for up to 120 days during the pendency of the J-1 principal alien's application for extension of stay. They felt that an automatic extension of up to 120 days would protect the J-2 dependents from the loss of employment during lengthy adjudications. Since the Service is currently making timely adjudications, typically, applications for extension of stay are turned around in less than 60 days, this suggestion was not adopted in the final rule. However, J-1 principal aliens may file for extension of stay 60 days prior to the expiration date, early filing of their applications for extension of stay is advised.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization Service certifies that this rule will not, if promulgated, have a significant adverse economic impact on a substantial number of small entities.

This rule is not considered to be a major rule within the meaning of section 1(b) of E.O. 12291, nor does this rule have Federalism implications warranting the preparation of a Federalism Assessment in accordance with E.O. 12612.

The information collection requirements contained in this rule have been cleared by the Office of Management and Budget under the provisions of the Paperwork Reduction Act. The OMB control numbers for these collections are contained in 8 CFR 299.5.

List of Subjects in 8 CFR Part 214

Administrative practice and procedure, Aliens, Authority delegation (Government agencies), Employment, Organization and functions (Government agencies).

Accordingly, part 214 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 214—NONIMMIGRANT CLASSES

1. The authority citation for part 214 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1184, 1186a, 1187, and 8 CFR part 2.

2. Section 214.2 is amended by revising paragraph (j)(1)(v) to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(j) * * *

(1) * * *

(v) *Employment.* (A) The accompanying spouse and minor children of a J-1 exchange visitor may accept employment only with authorization by the Immigration and Naturalization Service. A request for employment authorization must be made on Form I-765, Application for Employment Authorization, with fee, as required by 8 CFR 274a.12(c)(5), to the district director having jurisdiction over the J-1 exchange visitor's temporary residence in the United States. Income from the spouse's or dependent's employment may be used to support the family's customary recreational and cultural activities and related travel, among other things. Employment will not be authorized if this income is needed to support the J-1 principal alien.

(B) J-2 employment may be authorized for the duration of the J-1 principal alien's authorized stay as indicated on Form I-94 or a period of four years, whichever is shorter. The employment authorization is valid only if the J-1 is maintaining status. Where a J-2 spouse or dependent child has filed a timely application for extension of stay, only upon approval of the request for extension of stay may he or she apply for a renewal of the employment

authorization on a Form I-765 with the required fee.

* * * * *

Dated: May 20, 1991.

Gene McNary,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 91-17284 Filed 7-19-91; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91-NM-42-AD; Amdt. 39-7059; AD 91-14-18]

Airworthiness Directives; British Aerospace Viscount Model 744, 745D, and 810 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, clarification.

SUMMARY: This action clarifies the effective date of an airworthiness directive (AD), applicable to all British Aerospace Viscount Model 744, 745D, and 810 series airplanes, which requires repetitive eddy current inspections to detect corrosion along the total length of the top surface of the wing spar upper boom, and repair, if necessary. This action is prompted by an administrative error that resulted in a second publication of this AD in the Federal Register, with a different effective date.

DATES: Effective August 6, 1991.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 6, 1991.

ADDRESSES: The applicable service information may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041-0414. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 227-2148. Mailing address: FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

SUPPLEMENTARY INFORMATION: On June 18, 1991, the FAA issued AD 91-14-18, Amendment 39-7059, which was published in the Federal Register on July 2, 1991 (56 FR 30313). That AD is applicable to all British Aerospace Viscount Model 744, 745D, and 810 series airplanes, and requires repetitive eddy current inspections to detect corrosion along the total length of the top surface of the wing spar upper boom, and repair, if necessary, in accordance with British Aerospace Preliminary Technical Leaflet (PTL) No. 321, Issue 1, dated January 13, 1989, or PTL No. 190, Issue 1, dated January 13, 1989. The requirements of this AD are intended to preclude reduced structural integrity of the wings of these airplanes. As published in the Federal Register on July 2, 1991, the effective date for the AD was correctly specified as August 6, 1991.

Due to an administrative error, AD 91-14-18 was inadvertently published a second time in the Federal Register on July 9, 1991 (56 FR 31071). The second publication was identical to the first, except that the effective date was incorrectly specified as August 13, 1991.

Since the second publication of the rule was in error, action is taken herein to clarify that the correct effective date for AD 91-14-18, Amendment 39-7059, is August 6, 1991, as was indicated in the initial publication of the rule. There are no other changes to the rule.

Since this action only clarifies the effective date of a final rule, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and public procedures hereon are unnecessary.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

91-14-18. British Aerospace: Amendment 39-7059. Docket No. 91-NM-42-AD.

Applicability: All Viscount Model 744, 745D, and 810 series airplanes, certificated in any category.

Compliance: Required as indicated, unless previously accomplished. To prevent reduced structural integrity of the wings, accomplish the following:

A. Within 180 days after the effective date of this AD, and thereafter at intervals not to exceed 180 days, perform an eddy current inspection to detect corrosion along the total length of the top surface of the left and right wing spar upper boom in accordance with British Aerospace Preliminary Technical Leaflet (PTL) No. 321, Issue 1, dated January 13, 1989, or PTL No. 190, Issue 1, dated January 13, 1989, as applicable.

B. If corrosion is found, prior to further flight, repair in accordance with PTL No. 321, Issue 1, dated January 13, 1989, or PTL No. 190, Issue 1, dated January 13, 1989, as appropriate; or in a manner approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

C. An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

E. The inspections and repair requirements shall be done in accordance with British Aerospace Preliminary Technical Leaflet (PTL) No. 321, Issue 1, dated January 13, 1989 or PTL No. 190, Issue 1, dated January 13, 1989, as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041-0414. Copies may be inspected at the FAA, Transport Airplane Directorate, Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

This amendment (39-7059, AD 91-14-18) becomes effective August 6, 1991.

Issued in Renton, Washington, on July 12, 1991.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-17348 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 91-NM-47-AD; Amdt. 39-7060; AD 91-14-19]

Airworthiness Directives; British Aerospace Model BAe 146 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, clarification.

SUMMARY: This action clarifies the effective date of an airworthiness directive (AD), applicable to all British Aerospace Model BAe 146 series airplanes, which requires a detailed visual inspection to detect cracks and corrosion in the left and right main landing gear (MLG) door rear hinge bracket assemblies, and repair of corrosion or replacement of bracket, if necessary. This action is prompted by an administrative error that resulted in a second publication of this AD in the **Federal Register**, with a different effective date.

DATES: Effective August 6, 1991.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 6, 1991.

ADDRESSES: The applicable service information may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 227-2148. Mailing address: FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

SUPPLEMENTARY INFORMATION: On June 18, 1991, the FAA issued AD 91-14-19, Amendment 39-7060, which was published in the **Federal Register** on July 2, 1991 (56 FR 30314). That AD is applicable to all British Aerospace Model BAe 146 series airplanes, and requires a detailed visual inspection to detect cracks and corrosion in the left and right main landing gear (MLG) door rear hinge bracket assemblies, and repair of corrosion or replacement of the bracket, if necessary, in accordance with British Aerospace Alert Service Bulletin 32-A119, dated November 14, 1990. The requirements of this AD are intended to preclude the main landing gear (MLG) door from becoming detached in flight. As published in the **Federal Register** on July 2, 1991, the effective date for the AD was correctly specified as August 6, 1991.

Due to an administrative error, AD 91-14-19 was inadvertently published a second time in the **Federal Register** on July 9, 1991 (56 FR 31070). The second publication was identical to the first, except that the effective date was incorrectly shown as August 13, 1991.

Since the second publication of the rule was in error, action is taken herein to clarify that the correct effective date for AD 91-14-19, Amendment 39-7060, is August 6, 1991, as was indicated in the initial publication of the rule. There are no other changes to the rule.

Since this action only clarifies the effective date of a final rule, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and public procedures hereon are unnecessary.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

91-14-19. **British Aerospace:** Amendment 39-7060. Docket No. 91-NM-47-AD.

Applicability: All Model BAe 146 series airplanes, certificated in any category.

Compliance: Required as indicated, unless previously accomplished. To prevent detachment of the landing gear (MLG) door in flight, accomplish the following:

A. Prior to the accumulation of 6,000 landings or within 30 days after the effective date of this AD, whichever occurs later, perform a detailed visual inspection of the left and right MLG door rear hinge bracket assemblies, in accordance with British Aerospace Alert Service Bulletin 32-A119, dated November 14, 1990.

1. If cracks are found, prior to further flight, replace the rear hinge bracket assembly with a serviceable part having the same part number, in accordance with the service bulletin.

2. If corrosion is found, prior to further flight, remove corrosion and repair in accordance with the Structural Repair Manual 51-73-00 and Figure 1, section A-A.

a. If corrosion removed measures less than 0.150 inch, within 300 landings following repair, replace the rear hinge bracket assembly with a serviceable part having the same part number, in accordance with the service bulletin.

b. If corrosion removed measures 0.150 inch or more, prior to further flight, replace the rear hinge bracket assembly with a serviceable part having the same part number, in accordance with the service bulletin.

3. After repair, or if no corrosion is found, reseal bonding lead tags in accordance with Aircraft Maintenance Manual 20-10-01, Method 3.

B. Within 10 days after accomplishing the inspection required by paragraph A. of this AD, submit a written report of all findings to British Aerospace in accordance with paragraph 1.C.(5) of British Aerospace Alert Service Bulletin 32-A119, dated November 14, 1990. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and have been assigned OMB Control Number 2120-0056.

C. An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

E. The inspection and replacement requirements shall be done in accordance with British Aerospace Alert Service Bulletin 32-A119, dated November 14, 1990. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace, PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. Copies may be inspected at the FAA, Transport Airplane Directorate, Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

This amendment (39-7060, AD 91-14-19) becomes effective August 6, 1991.

Issued in Renton, Washington, on July 12, 1991.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-17349 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 91-NM-35-AD; Amdt. 39-7058; AD 91-14-17]

Airworthiness Directives; SAAB-Scania Models SF-340A and SAAB 340B Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, clarification.

SUMMARY: This action clarifies the effective date of an airworthiness directive (AD), applicable to certain SAAB-Scania Models SF-340A and SAAB 340B series airplanes, which requires replacement of a wire in the autopilot electrical system. This action is prompted by an administrative error that resulted in a second publication of this AD in the Federal Register, with a different effective date.

DATES: Effective August 6, 1991.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 6, 1991.

ADDRESSES: The applicable service information may be obtained from SAAB-Scania AB, Product Support, S-581.88, Linköping, Sweden. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Quam, Standardization Branch, ANM-113; telephone (206) 227-2145. Mailing address: FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

SUPPLEMENTARY INFORMATION: On June 18, 1991, the FAA issued AD 91-14-17, Amendment 39-7058, which was published in the Federal Register on July 2, 1991 (56 FR 30315). That AD is applicable to certain SAAB-Scania Models SF-340A and SAAB 340B series airplanes, and requires the replacement of a wire in the autopilot electrical system in accordance with SAAB Service Bulletin 340-34-068, dated November 9, 1991. The requirements of this AD are intended to preclude the possibility of an electrical fire and smoke in the cockpit. As published in the Federal Register on July 2, 1991, the effective date for the AD was correctly specified as August 6, 1991.

Due to an administrative error, AD 91-14-17 was inadvertently published a second time in the Federal Register on July 9, 1991 (56 FR 31072). The second publication was identical to the first, except that the effective date was incorrectly specified as August 13, 1991.

Since the second publication of the rule was in error, action is taken herein to clarify that the correct effective date for AD 91-14-17, Amendment 39-7058, is August 6, 1991, as was indicated in the initial publication of the rule. There are no other changes to the rule.

Since this action only clarifies the effective date of a final rule, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and public procedures hereon are unnecessary.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

91-14-17. **SAAB-Scania:** Amendment 39-7058. Docket No. 91-NM-35-AD.

Applicability: Model SF-340A series airplanes, Serial Numbers 079 through 159; and Model SAAB 340B series airplanes, Serial Numbers 160 through 199; certificated in any category.

Compliance: Required within 180 days after the effective date of this AD, unless previously accomplished.

To prevent an electrical fire and smoke in the cockpit, accomplish the following:

A. Replace the FD 574-24 wire from terminal block 301VT BH:C to connector 203VU P33:A1 in the autopilot electrical system with a 20 AWG size wire, in accordance with SAAB Service Bulletin 340-34-068, dated November 9, 1990.

B. An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

Note: The request should be forwarded through an FAA Principal Avionics Inspector, who may concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

D. The replacement requirements shall be done in accordance with SAAB Service Bulletin 340-34-068, dated November 9, 1990. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from SAAB-Scania AB, Product Support, S-581.88, Linköping, Sweden. Copies may be inspected at the FAA, Transport Airplane Directorate, Renton, Washington; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

This amendment (39-7058, AD 91-14-17) becomes effective August 6, 1991. Issued in Renton, Washington, on July 12, 1991.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-17350 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 91-AWP-5]

Amendment of the Red Bluff, CA, Control Zone

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment to the Red Bluff, CA, Control Zone will change the effective hours of the control zone. The Red Bluff, CA, Control Zone does not meet full-time control zone criteria and thus the need for an amendment to a part-time control zone.

EFFECTIVE DATE: 0901 u.t.c., October 17, 1991

FURTHER INFORMATION CONTACT: Mr. Tom Bowman, Airspace Specialist, System Management Branch, AWP-530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261; telephone: (213) 297-0433.

SUPPLEMENTARY INFORMATION:

History

On May 24, 1991, the FAA proposed to amend § 71.171 of part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the effective hours of the Red Bluff, CA, Control Zone (56 FR 23820).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

The Rule

This amendment to § 71.171 of part 71 of the Federal Aviation Regulations amends the effective hours of the Red Bluff, CA, Control Zone.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zones

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 71 of the Federal Aviation Regulations (14 CFR part 71) is amended as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.171 [Amended]

2. Section 71.171 is amended as follows:

Red Bluff, CA [Revised]

Within a 5-mile radius of Red Bluff Municipal Airport (lat. 40°09'04" N., long. 122°15'05" W.) and within 2 miles each side of the Red Bluff VORTAC 167° radial, extending from the 5-mile radius zone to 8 miles south of the VORTAC. This control zone is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in Los Angeles, California, on July 5, 1991.

Richard R. Lien,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 91-17328 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 75

[Airspace Docket No. 90-AGL-19]

Alteration of Jet Route J-63

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment alters the description of Jet Route J-63 located in the states of New York and Michigan. The alteration to this jet route establishes an extension to the route from Syracuse, NY, to Traverse City, MI. This action provides for optimum use of the route structure and improves the flow of air traffic.

EFFECTIVE DATE: 0901 u.t.c., September 19, 1991.

FOR FURTHER INFORMATION CONTACT: Patricia P. Crawford, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9255.

SUPPLEMENTARY INFORMATION:

History

On January 10, 1991, the FAA proposed to amend part 75 of the Federal Aviation Regulations (14 CFR part 75) to alter the description of J-63 located in the states of New York and Michigan (56 FR 975). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 75.100 of part 75 of the Federal Aviation Regulations was republished in Handbook 7400.6G dated September 4, 1990.

The Rule

This amendment to part 75 of the Federal Aviation Regulations alters J-63 located in the states of New York and Michigan. Modifying J-63 will establish an extension to the jet route from Syracuse, NY, to Traverse City, MI. Adjustment to this jet route will facilitate the air traffic flow, conserve fuel, minimize en route delays and reduce the controller workload.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 75

Aviation safety, Jet routes.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 75 of the Federal Aviation Regulations (14 CFR part 75) is amended, as follows:

PART 75—ESTABLISHMENT OF JET ROUTES AND AREA HIGH ROUTES

1. The authority citation for part 75 continues to read as follows:

Authority: 49 U.S.C. App. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 75.100 [Amended]

2. Section 75.100 is amended as follows:

J-63 [Revised]

From Kennedy, NY, via Huguenot, NY; INT of Huguenot 321° and Syracuse, NY, 149° radials; Syracuse; INT Syracuse 270° and Waterloo, Ontario, Canada 101° radials; Waterloo; Au Sable, MI; to Traverse City, MI. The airspace within Canada is excluded.

Issued in Washington, DC, on July 12, 1991

Jerry W. Ball,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 91-17330 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 75

[Airspace Docket No. 90-ASO-17]

Alteration of Jet Route J-121; SC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment alters the description of Jet Route J-121 located in the vicinity of Charleston, SC. Under the current route alignment, a minimum en route altitude (MEA) signal gap exists in the route segment between Charleston, SC, and Norfolk, VA. This action eliminates this gap by adding the

Kinston, NC, VOR to the description of J-121, thereby improving navigation in the area.

EFFECTIVE DATE: 0901 u.t.c., September 19, 1991.

FOR FURTHER INFORMATION CONTACT: Lewis Still, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9250.

SUPPLEMENTARY INFORMATION:

History

On October 30, 1990, the FAA proposed to amend part 75 of the Federal Aviation Regulations (14 CFR part 75) to alter the description of Jet Route J-121 located in the vicinity of Charleston, SC, by adding the Kinston, NC, VOR to the route alignment between Charleston, SC, and Norfolk, VA (55 FR 45614). Under the current alignment of this segment, a MEA signal gap exists. Adding Kinston, NC, VOR to the route segment will eliminate this signal problem. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 75.100 of part 75 of the Federal Aviation Regulations was republished in Handbook 7400.6G dated September 4, 1990.

The Rule

This amendment to part 75 of the Federal Aviation Regulations alters the description of Jet Route J-121 located in the vicinity of Charleston, SC. Under the current route alignment, a MEA signal gap exists in the route segment between Charleston, SC, and Norfolk, VA. This action will eliminate this gap by adding the Kinston, NC, VOR to the description of J-121, thereby improving navigation in the area.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 75

Aviation safety, Jet routes.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 75 of the Federal Aviation Regulations (14 CFR part 75) is amended, as follows:

PART 75—ESTABLISHMENT OF JET ROUTES AND AREA HIGH ROUTES

1. The authority citation for part 75 continues to read as follows:

Authority: 49 U.S.C. App. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 75.100 [Amended]

2. Section 75.100 is amended as follows:

J-121 [Amended]

By removing the words "Charleston; Norfolk, VA;" and substituting the words "Charleston; Kinston, NC; Norfolk, VA;"

Issued in Washington, D.C., on July 12, 1991.

Jerry W. Ball,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 91-17329 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB 91]

Staff Accounting Bulletin No. 91

AGENCY: Securities and Exchange Commission.

ACTION: Publication of Staff Accounting Bulletin.

SUMMARY: Staff Accounting Bulletin No. 91 ("SAB 91"), which was released on July 17, 1991, expresses the staff's views regarding the accounting for income tax benefits of thrift bad debt losses. This staff accounting bulletin is intended to serve as interim guidance until a new standard on accounting for income taxes is adopted.

FOR FURTHER INFORMATION CONTACT: Margaret Ruffin Horvath, Office of the Chief Accountant (202-272-2130); or Robert A. Bayless, Division of Corporation Finance (202-272-2553); Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The statements in staff accounting bulletins are not rules or interpretations of the Commission nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

Dated: July 17, 1991.

Margaret H. McFarland,

Deputy Secretary.

Accordingly, part 211 of title 17 of the Code of Federal Regulations is amended by adding Staff Accounting Bulletin No. 91 to the table found in subpart B.

Staff Accounting Bulletin No. 91

The staff hereby adds section X to Topic 5 of the Staff Accounting Bulletin Series. Topic 5-X discusses accounting for the income tax benefits associated with bad debts of thrifts.

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Topic 5: Miscellaneous Accounting

* * * * *

X. Accounting for Income Tax Benefits Associated with Bad Debts of Thrifts

Facts: The tax code provides thrifts with a deduction for bad debts based on a percentage of taxable income ("PTI"). For many years, actual bad debt losses were far less than the PTI deduction available to most thrifts. Consequently, many thrifts accumulated a large tax reserve for bad debts. The tax code limits the recapture of the benefit provided the thrifts through PTI deductions to events which typically are controlled by the thrift's management (such as the payment of excess dividends or the failure to meet thrift definitional tests). As a result, Accounting Principles Board ("APB") Opinion No. 23 does not require thrifts to provide deferred income taxes related to the difference between taxable income and pretax accounting income attributable to a reserve for bad debts until it is likely that taxes will be paid.

Recent economic conditions in the industry have significantly increased the actual bad debt losses experienced by many thrifts. In addition, the Tax Reform Act of 1986 ("TRA 86") reduced the amount of PTI deduction available to thrifts. The resulting increases in the bad debt reserve for financial reporting purposes ("book reserve") have focused attention on the accounting for the

potential tax benefit that may arise in future periods when the book reserve is deducted for tax purposes.

Some thrifts have interpreted the guidance in APB Opinion No. 23 to apply only to the deferred income tax liability related to the bad debt reserve for tax purposes ("tax reserve") and not to the book reserve. Under this interpretation, referred to as the "two-difference method" by those applying Statement of Financial Accounting Standards ("SFAS") No. 96 and the "annual method" by those applying APB Opinion No. 11, deferred income taxes related to the tax reserve are not recognized but income tax benefits related to some or all of the book reserve are recognized. Other thrifts have interpreted the guidance in APB Opinion No. 23 to prohibit recognition of a deferred tax benefit related to the book reserve if a deferred tax liability has not been recognized related to the tax reserve (referred to as the "one-difference" or "cumulative" method by those applying SFAS No. 96 and APB Opinion No. 11, respectively). Still other thrifts have applied variations of these methods.

Members of the accounting profession acknowledged that practice was diverse on accounting for deferred income taxes related to reserves for bad debts of thrifts and referred the issue to the FASB's Emerging Issues Task Force ("EITF"). The EITF discussed the issue (Issue No. 91-3) on May 9, 1991 and did not reach a consensus as to the preferability of the methods. However, at the meeting, the FASB staff announced its belief "* * * that no tax benefit may be recognized in income unless and until the book bad debt reserve exceeds the tax bad debt reserve." The FASB staff position was supported by the Financial Accounting Standard Board's ("Board") tentative decision, related to a proposed statement that would supersede SFAS No. 96, "* * * that the difference between a thrift's book bad debt reserve and tax bad debt reserve is a single temporary difference." [1]

Because uncertainty regarding the alternative accounting methods was not resolved by the EITF and continuation of the present diversity of accounting practices reduces the comparability and reliability of financial reporting by thrifts, the staff is publishing its interpretation of the current accounting literature to serve as interim guidance for public companies until a new standard on accounting for income taxes is adopted.

Question 1: Is it appropriate for a thrift to recognize the deferred income tax benefits associated with its book reserve when the thrift has not recognized the deferred income tax liability related to its tax reserve?

Interpretive Response: No. The staff believes that the difference between the book and tax reserves represents a single timing or temporary difference. As the staff stated at the May 9, 1991 EITF meeting, the staff will challenge the preferability of the adoption of the two-difference or annual method after May 9, 1991, including the initial selection of either method in an initial public offering.

However, if a thrift's book reserve exceeds its tax reserve, the staff would not object to the recognition of the income tax benefit related to the excess, as long as there is a likelihood that future benefits will result.[2]

Question 2: If a thrift's existing practice with respect to accounting for the income tax benefits of bad debts differs from the staff's interpretation, must the thrift adopt the one-difference or cumulative method through restatement of prior periods?

Interpretive Response: No. The staff will not object if a thrift adopts the one-difference or cumulative method prospectively for periods beginning on or after July 1, 1991, without restatement of prior periods, provided the disclosures noted below in Question 3 are provided by the thrift. However, the staff encourages thrifts to account for the change to the one-difference or cumulative method as a change in accounting principle in accordance with the accounting and disclosure guidance provided in paragraphs 18 through 22 of APB Opinion No. 20. The reversal of income tax benefits that were recognized previously would be included in the cumulative effect of the change in accounting principle. Alternatively, the staff encourages retroactive restatement of previously filed financial statements.

Question 3: If a thrift adopts the one-difference or cumulative method prospectively, rather than as a cumulative adjustment or through retroactive restatement, what disclosures regarding the tax benefit recognized under the two-difference or annual method should be included in the financial statements?

Interpretive Response: To facilitate comparability of financial statements among thrifts, the staff believes that those institutions that adopt the one-difference or cumulative method prospectively should include the following in a note to financial statements filed with the Commission, in addition to the disclosure requirements of APB Opinion No. 23 and SFAS No. 96:

a. A description of the method used in calculating deferred income taxes related to bad debts and the date the method was adopted initially. If the method used by the registrant differs from the methods described in the EITF Issue Summary 91-3, this should be disclosed and the effect quantified;

b. The amount of the income tax benefit included in the latest balance sheet presented that is attributable to the use of the two-difference or annual method, as compared to the use of the one-difference or cumulative method;

c. Quantification of the effect on net income and earnings per share, in each period for which an operating statement is presented, of applying the two-difference or annual method as compared to the one-difference or cumulative method, as applicable; and,

d. Discussion of the tentative decision reached by the FASB that the difference between the tax and financial reporting basis of a thrift's bad debt reserves is a single temporary difference and the effect that decision will have, if adopted in final form, on net income, earnings per share and stockholder's equity.

Question 4: If a thrift, following the guidance in this SAB, adopts the one-difference or cumulative method prospectively, will the income tax benefits previously recognized under the two-difference or annual method reverse?

Interpretive Response: Yes. The amount of previously recognized income tax benefits related to the book reserve should not be "frozen" on the balance sheet. The deferred tax benefits should be subject to reversal when realized.

Question 5: How does the staff's interpretation affect the accounting for the potential consequences of the difference between the book and tax reserve for bad debts as specified in APB Opinion No. 23?

Interpretive Response: Paragraph 23 of APB Opinion No. 23 specifies that deferred income taxes do not have to be provided for differences between the taxable income and pretax accounting income related to bad debts unless "the association is likely to pay income

[1] On May 2, 1991, as reported in the minutes of the May 9, 1991 open meeting of the EITF, the FASB tentatively concluded that "* * * a potential deferred tax asset would be recognized only if the difference between the tax bad debt reserve and the book bad debt reserve is a net deductible temporary difference." The tentative decision was reached during deliberations on the proposed statement that will supersede SFAS No. 96 which was exposed for public comment on June 5, 1991. The final statement is expected to be issued during the first quarter of 1992.

[2] SAB Topic 5-C.2, "Realization of Tax Benefit," addresses the conditions that must be met in order to record a deferred tax benefit.

taxes, either currently or in later years, because of known or expected reductions in the bad debt reserve." The staff's interpretation does not change that guidance; however, due to changes in the tax law occurring in 1986,[3] the staff believes that, currently, there is a presumption that taxes will be paid on any increase in the tax bad debt reserve in excess of the base-year tax reserve.

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 37

[Docket No. RM90-12-000]

Generic Determination of Rate of Return on Common Equity for Public Utilities

July 15, 1991.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of benchmark rate of return on common equity for public utilities.

SUMMARY: In accordance with § 37.5 of its regulations, the Federal Energy Regulatory Commission, by its designee, the Director of the Office of Economic Policy, issues the update to the benchmark rate of return on common equity applicable to rate filings made during the period August 1, 1991 through October 31, 1991. This benchmark rate is set at 11.72 percent.

EFFECTIVE DATE: August 1, 1991.

FOR FURTHER INFORMATION CONTACT: Marvin Rosenberg, Office of Economic Policy, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208-1283.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3308 at the Commission's Headquarters, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200, or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this final rule will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

On December 26, 1990, the Federal Energy Regulatory Commission (Commission) issued a final rule (Order No. 532) concerning the generic determination of the rate of return on common equity for public utilities.[1] In several earlier rulemaking proceedings, the Commission established a discounted cash flow (DCF) formula to determine the average cost of common equity and a quarterly indexing procedure to calculate benchmark rates of return on common equity for public utilities and codified the formula and procedure at § 37.9 of its regulations.[2] In Order No. 532, the Commission determined that 4.3 percent is an appropriate expected annual dividend growth rate for use in the quarterly indexing procedure during the 12 months beginning February 1, 1991 and that 0.02 percent is an appropriate flotation cost adjustment factor for that period.

The Commission, by its designee, the Director of the Office of Economic Policy, uses the quarterly indexing procedure to determine that the benchmark rate of return on common equity applicable to rate filings made during the period August 1, 1991 through October 31, 1991 is 11.72 percent.

Section 37.9 of the Commission's regulations requires that the quarterly benchmark rate of return be set equal to the average cost of common equity for the jurisdictional operations of public utilities. This average cost is based on the average of the median dividend yields for the two most recent calendar quarters for a sample of 97 utilities. The average yield is used in the following formula with fixed adjustment factors (determined in the most recent annual proceeding) to determine the cost rate:

$$k_t = 1.02\ Y_t + 4.32$$

Where k_t is the average cost of common equity and Y_t is the average dividend yield.

The attached appendix provides the supporting data for this update. The median dividend yields for the sample of utilities for the first and second quarters of 1991 are 7.43 percent and 7.06, respectively. The average yield for those two quarters is 7.25 percent. Use of the average dividend yield in the above formula produces an average cost of common equity of 11.72 percent.

This notice supplements the generic rate of return rule announced in Order No. 532, issued December 26, 1990 and effective on February 1, 1991.

List of Subjects in 18 CFR Part 37

Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission amends part 37, chapter I, Title 18 of the Code of Federal Regulations, as set forth below, effective August 1, 1991.

Richard P. O'Neill,

Director, Office of Economic Policy.

PART 37—GENERIC DETERMINATION OF RATE OF RETURN ON COMMON EQUITY FOR PUBLIC UTILITIES

1. The authority citation for part 37 continues to read as follows:

Authority: Federal Power Act, 16 U.S.C. 791a-825r (1982); Department of Energy Organization Act, 42 U.S.C. 7101-7352 (1982).

2. In § 37.9, paragraph (d) is revised to read as follows:

§ 37.9 Quarterly indexing procedure.

* * * * *

(d) *Table of Quarterly Benchmark Rates of Return.*

The following table presents the quarterly benchmark rates of return on common equity:

[3] TRA 86 provides for the potential recapture of PTI deductions added to the tax reserve in excess of the "base-year tax reserve" (as defined in TRA 86).

[1] Generic Determination of Rate of Return on Common Equity for Public Utilities, Order No. 532, 56 FR 10 (Jan. 2, 1991), Order No. 532, III FERC Statutes and Regulations ¶ 30,909 (1991).

[2] 18 CFR 37.9 (1990). The most recent adoption of the DCF formula and quarterly indexing procedure came in Order No. 489, 53 FR 3342 (Feb. 5, 1988).

Benchmark applicability period (t)	Dividend increase adjustment factor (a)	Expected growth adjustment factor (b)	Current dividend yield (Y_j)	Cost of common equity (k_e)	Benchmark rate of return
2/1/86-4/30/86	1.02	4.54	9.03	13.75	13.75
5/1/86-7/31/86	1.02	4.54	8.37	13.08	13.25
8/1/86-10/31/86	1.02	4.54	7.49	12.18	12.75
11/1/86-1/31/87	1.02	4.54	6.75	11.43	12.25
2/1/87-4/30/87	1.02	4.63	6.44	11.20	11.20
5/1/87-7/31/87	1.02	4.63	6.54	11.30	11.30
8/1/87-10/31/87	1.02	4.63	6.97	11.74	11.74
11/1/87-1/31/88	1.02	4.63	7.49	12.27	12.27
2/1/88-4/30/88	1.02	4.36	7.90	12.42	12.42
5/1/88-7/31/88	1.02	4.36	7.99	12.51	12.51
8/1/88-10/31/88	1.02	4.36	7.84	12.36	12.36
11/1/88-1/31/89	1.02	4.36	7.92	12.44	12.44
2/1/89-4/30/89	1.02	4.33	7.89	12.38	12.38
5/1/89-7/31/89	1.02	4.33	7.95	12.44	12.44
8/1/89-10/31/89	1.02	4.33	7.94	12.43	12.43
11/1/89-1/31/90	1.02	4.33	7.56	12.04	12.04
2/1/90-4/30/90	1.02	4.32	7.28	11.75	11.75
5/1/90-7/31/90	1.02	4.32	7.38	11.85	11.85
8/1/90-10/31/90	1.02	4.32	7.59	12.06	12.06
11/1/90-1/31/91	1.02	4.32	7.81	12.29	12.29
2/1/91-4/30/91	1.02	4.32	7.80	12.28	12.28
5/1/91-7/31/91	1.02	4.32	7.55	12.02	12.02
8/1/91-10/31/91	1.02	4.32	7.25	11.72	11.72

Note: The Appendix will not be published in Code of Federal Regulations

Appendix

Exhibit No., and Title

1—Initial sample of utilities
2—Utilities excluded from the sample for the indicated quarter due to either zero dividends or a reduction in dividends for this quarter or the prior three quarters
3—Annualized dividend yields for the indicated quarter for utilities retained in the sample

Source of Data: Standard and Poor's Compustat Services, Inc., Utility COMPUSTAT II Quarterly Data Base.

EXHIBIT 1.—SAMPLE OF UTILITIES

Utility	Ticker symbol	Industry code
Allegheny Power System	AYP	4911
American Electric Power	AEP	4911
Atlantic Energy Inc.	ATE	4911
Baltimore Gas & Electric	BGE	4931
Black Hills Corp	BKH	4911
Boston Edison Co.	BSE	4911
Carolina Power & Light	CPL	4911
Centerior Energy Corp	CX	4911
Central & South West Corp	CSR	4911
Central Hudson Gas & Electric.	CNH	4931
Central Louisiana Electric	CNL	4911
Central Maine Power Co.	CTP	4911
Central Vermont Pub Serv	CV	4911
Cilcorp Inc	CER	4931
Cincinnati Gas & Electric	CIN	4931
Cipsco Inc	CIP	4931
CMS Energy Corp	CMS	4931
Commonwealth Edison	CWE	4911
Commonwealth Energy Syste	CES	4931
Consolidated Edison of NY	ED	4931

EXHIBIT 1.—SAMPLE OF UTILITIES—Continued

Utility	Ticker symbol	Industry code
Delmarva Power & Light	DEW	4931
Detroit Edison Co	DTE	4911
Dominion Resources Inc	D	4931
DPL Inc	DPL	4931
DQE Inc	DQE	4911
Duke Power Co	DUK	4911
Eastern Utilities Assoc	EUA	4911
Empire District Electric	EDE	4911
Entergy Corp	ETR	4911
Fitchburg Gas & Elec Ligh	FGE	4931
Florida Progress Corp	FPC	4911
FPL Group Inc	FPL	4911
General Public Utilities	GPU	4911
Green Mountain Power Corp	GMP	4911
Gulf States Utilities Co	GSU	4911
Hawaiian Electric Inds	HE	4911
Houston Industries Inc	HOU	4911
I E Industries Inc	IEL	4931
Idaho Power Co	IDA	4911
Illinois Power Co	IPC	4931
Interstate Power Co	IPW	4931
Iowa-Illinois Gas & Elec	IWG	4931
Ipalco Enterprises Inc	IPL	4911
Kansas City Power & Light	KLT	4911
Kansas Gas & Electric	KGE	4911
Kansas Power & Light	KAN	4931
Kentucky Utilities Co	KU	4911
LG&E Energy Corp	LGE	4931
Long Island Lighting	LIL	4931
Maine Public Service	MAP	4911
Midwest Resources	MWR	4931
Minnesota Power & Light	MPL	4911
Montana Power Co	MTP	4931
Nevada Power Co	NVP	4911
New England Electric Syst	NES	4911
New York State Elec & Gas	NGE	4931
Niagara Mohawk Power	NMK	4931
NIPSCO Industries Inc	NI	4931
Northeast Utilities	NU	4911

EXHIBIT 1.—SAMPLE OF UTILITIES—Continued

Utility	Ticker symbol	Industry code
Northern States Power-MN	NSP	4931
Northwestern Public Serv	NPS	4931
Ohio Edison Co	OEC	4911
Oklahoma Gas & Electric	OGE	4911
Orange & Rockland Utiliti	ORU	4931
Pacific Gas & Electric	PCG	4931
Pacificorp	PPW	4931
Pennsylvania Power & Ligh	PPL	4911
Philadelphia Electric Co	PE	4931
Pinnacle West Capital	PNW	4911
Portland General Corp	PGN	4911
Potomac Electric Power	POM	4911
PSI Resources Inc	PIN	4911
Public Service Co of Colo	PSR	4931
Public Service Co of NH	PNH	4911
Public Service Co of N ME	PNM	4931
Public Service Entrp	PEG	4931
Puget Sound Power & Light	PSD	4911
Rochester Gas & Electric	RGS	4931
San Diego Gas & Electric	SDO	4931
Scana Corp	SCG	4931
Scecorp	SCE	4911
Sierra Pacific Res	SRP	4931
Southern Co	SO	4911
Southern Indiana Gas & El	SIG	4931
St Joseph Light & Power	SAJ	4931
Teco Energy Inc	TE	4911
Texas Utilities Co	TXU	4911
TNP Enterprises Inc	TNP	4911
Tucson Electric Power Co	TEP	4911
Union Electric Co	UEP	4911
United Illuminating Co	UIL	4911
Unitil Corp	UTL	4911
Utilicorp United Inc	UCU	4931
Washington Water Power	WWP	4931
Wisconsin Energy Corp	WEC	4931
Wisconsin Public Service	WPS	4931
WPL Holdings Inc	WPH	4931

N=97.

EXHIBIT 2.— UTILITIES EXCLUDED FROM THE SAMPLE FOR THE INDICATED QUARTER DUE TO EITHER ZERO DIVIDENDS OR A CUT IN THE DIVIDENDS FOR THIS QUARTER OR THE PRIOR THREE QUARTERS

[Year=91, Quarter=2]

Ticker symbol	Utility	Reason for exclusion
EUA	Eastern Utilities Assoc	Dividend rate was reduced for the quarter 91Q?
GSU	Gulf States Utilities Co	Dividend rate was zero for quarter 91Q2.
IPC	Illinois Power Co	Dividend rate was zero for quarter 91Q2.
MWR	Midwest Resources	Insufficient history of dividends.
NMK	Niagara Mohawk Power	Dividend rate was zero for quarter 91Q2.
OEC	Ohio Edison Co	Dividend rate was reduced for the quarter 90Q3.
PNW	Pinnacle West Capital	Dividend rate was zero for quarter 91Q2.
PNH	Public Service Co of NH	NYSE suspended trading on May 17, 1991.
PNM	Public Service Co of N ME	Dividend rate was zero for quarter 91Q2.
TEP	Tucson Electric Power Co	Dividend rate was zero for quarter 91Q2.

N=10.

EXHIBIT 3.—ANNUALIZED DIVIDEND YIELDS FOR THE INDICATED QUARTER FOR UTILITIES RETAINED IN THE SAMPLE

[Year=91, Quarter=2]

Ticker Symbol	Price, 1st Month of Qtr-High	Price, 1st Month of Qtr-Low	Price, 2nd Month of Qtr-High	Price, 2nd Month of Qtr-Low	Price, 3rd Month of Qtr-High	Price, 3rd Month of Qtr-Low	Average Price	Dividends Annual Rate	Annualized Dividend Yield
AEP	30.375	29.125	30.125	27.875	29.000	28.000	29.083	2.400	8.252
ATE	37.250	35.750	36.875	34.250	35.000	33.750	35.479	3.000	8.456
AYP	39.375	38.500	39.625	38.750	39.625	37.375	38.875	3.160	8.129
BGE	29.375	28.125	29.875	28.875	29.500	28.500	29.042	2.100	7.231
BKH	37.625	34.500	37.625	34.625	36.625	33.750	35.792	1.760	4.917
BSE	20.625	19.500	20.625	19.625	20.125	19.125	19.938	1.580	7.925
CER	34.750	32.875	34.750	32.500	34.250	32.125	33.542	2.460	7.334
CES	33.125	32.000	35.000	32.375	34.250	30.750	32.917	2.920	8.871
CIN	33.750	31.500	32.375	31.125	32.375	31.375	32.083	2.480	7.730
CIP	24.625	23.250	25.000	23.375	24.750	22.875	23.979	1.880	7.840
CMS	30.750	27.750	29.125	23.750	27.500	25.000	27.313	0.480	1.757
CNH	25.375	23.875	25.125	24.625	25.125	23.750	24.646	1.840	7.466
CNL	40.625	37.625	40.750	40.000	40.625	39.000	39.771	2.680	6.739
CPL	48.750	47.000	47.875	45.000	46.500	44.125	46.542	3.040	6.532
CSR	47.125	44.750	47.000	43.750	45.875	43.375	45.313	2.920	6.444
CTP	19.125	16.625	18.250	16.875	17.875	17.375	17.688	1.560	8.820
CV	27.375	25.750	26.000	26.625	28.875	26.375	27.167	2.080	7.656
CWE	40.000	37.625	39.125	36.125	38.000	36.000	37.813	3.000	7.934
CX	19.875	17.625	18.000	17.000	17.625	16.250	17.729	1.600	9.025
D	48.500	46.500	48.750	46.875	47.625	46.250	47.417	3.440	7.255
DEW	19.250	17.875	18.750	18.000	18.875	18.125	18.479	1.540	8.334
DPL	22.000	20.500	21.625	20.625	21.125	20.000	20.979	1.620	7.722
DQE	26.625	25.000	26.625	25.250	26.375	25.250	25.854	1.440	5.570
DTE	30.375	28.125	29.750	28.250	29.125	28.000	28.938	1.880	6.497
DUK	29.375	27.625	28.625	27.250	28.625	27.375	28.146	1.640	5.827
ED	25.875	24.250	25.375	23.000	24.875	23.625	24.500	1.860	7.592
EDE	35.500	33.250	36.000	34.500	35.500	34.000	34.792	2.420	6.956
ETR	25.000	23.375	25.000	23.875	24.125	23.125	24.083	1.200	4.983
FGE	30.750	29.250	31.000	28.875	31.750	29.250	30.146	2.120	7.032
FPC	41.750	39.625	41.000	39.375	39.750	38.875	40.063	2.740	6.839
FPL	30.750	29.750	31.875	29.875	30.625	29.625	30.417	2.400	7.890
GMP	26.000	25.000	27.125	25.750	26.625	25.125	25.938	2.020	7.788
GPU	24.875	23.750	24.375	23.000	23.750	22.375	23.688	1.500	6.332
HE	34.875	32.250	36.500	34.375	35.500	31.375	34.146	2.200	6.443
HOU	37.875	35.875	38.625	36.375	36.750	35.000	36.750	2.960	8.054
IDA	27.250	25.625	26.375	25.250	25.875	24.250	25.771	1.860	7.217
IEL	28.625	27.500	27.875	27.125	27.500	26.000	27.438	2.100	7.654
IPL	29.125	27.125	28.500	27.000	27.750	27.000	27.750	1.880	6.775
IPW	29.750	28.375	30.375	28.375	30.250	29.375	29.417	2.040	6.935
IWG	22.000	21.000	22.250	21.625	22.250	21.750	21.813	1.710	7.840
KAN	25.250	23.500	24.750	23.750	24.000	23.375	24.104	1.860	7.717
KGE	28.250	26.500	28.500	27.625	28.125	27.125	27.688	1.720	6.212
KLT	38.250	35.375	38.750	36.875	37.375	36.625	37.208	2.680	7.203
KU	22.750	21.125	22.750	21.750	22.625	21.500	22.083	1.500	6.792
LGE	40.875	39.750	40.875	40.000	41.375	39.500	40.396	2.840	7.030
LIL	23.500	22.375	23.625	22.000	22.875	21.500	22.646	1.500	6.624
MAP	25.000	22.500	23.500	22.500	23.375	21.625	23.083	1.680	7.278
MPL	29.000	27.000	29.125	28.000	29.250	26.500	28.146	1.900	6.751
MTP	22.875	21.625	23.250	21.875	22.875	22.000	22.417	1.480	6.602
NES	28.500	26.875	29.375	27.875	29.000	27.625	28.208	2.080	7.374
NGE	27.000	24.875	25.500	24.750	25.250	24.000	25.229	2.080	8.244
NI	21.125	19.750	21.750	20.000	21.375	20.375	20.729	1.160	5.596
NPS	25.000	23.375	25.375	23.375	25.625	24.750	24.583	1.520	6.183
NSP	35.625	33.000	34.375	33.000	34.875	33.125	34.000	2.320	6.824
NU	21.375	20.000	21.500	20.000	20.625	19.750	20.542	1.760	8.568

EXHIBIT 3.—ANNUALIZED DIVIDEND YIELDS FOR THE INDICATED QUARTER FOR UTILITIES RETAINED IN THE SAMPLE—Continued

[Year=91, Quarter=2]

Ticker Symbol	Price, 1st Month of Qtr-High	Price, 1st Month of Qtr-Low	Price, 2nd Month of Qtr-High	Price, 2nd Month of Qtr-Low	Price, 3rd Month of Qtr-High	Price, 3rd Month of Qtr-Low	Average Price	Dividends Annual Rate	Annualized Dividend Yield
NVP	21.750	20.250	21.250	19.750	20.000	16.875	19.979	1.600	8.008
OGE	40.500	38.875	40.500	36.750	38.500	37.000	38.688	2.580	6.669
ORU	33.750	32.125	34.250	32.750	35.000	33.000	33.479	2.340	6.989
PCG	27.375	25.375	27.375	25.500	26.000	24.750	26.063	1.640	6.293
PE	21.000	19.500	20.750	19.875	20.500	19.625	20.208	1.200	5.938
PEG	27.625	26.250	27.875	26.625	26.625	25.250	26.708	2.120	7.938
PGN	18.875	17.875	18.750	17.875	18.500	17.375	18.208	1.200	6.590
PIN	18.125	16.875	17.375	16.375	16.500	15.375	16.771	0.880	5.247
POM	22.250	21.125	22.000	20.625	21.125	20.125	21.208	1.560	7.356
PPL	46.125	43.750	45.500	44.000	44.875	42.625	44.479	3.100	6.970
PPW	23.000	21.125	22.000	20.625	21.250	20.500	21.417	1.440	6.724
PSD	23.000	21.500	22.875	21.500	22.625	21.750	22.208	1.760	7.925
PSR	24.000	22.750	24.000	21.000	22.875	20.875	22.583	2.000	8.856
RGS	20.500	19.000	20.250	19.500	19.875	19.250	19.729	1.620	8.211
SAJ	32.000	28.750	30.000	28.625	29.500	28.375	29.542	1.660	5.619
SCE	39.375	38.000	39.750	38.500	39.750	38.500	38.979	2.720	6.978
SCG	38.000	36.500	38.000	36.750	37.625	35.750	37.104	2.620	7.061
SDO	45.500	43.125	45.250	37.625	38.250	37.250	41.167	2.800	6.802
SIG	35.875	33.250	37.125	35.125	36.875	35.000	35.542	2.000	5.627
SO	28.750	26.875	27.750	26.625	28.125	26.125	27.375	2.140	7,817
SRP	23.000	22.000	23.500	21.625	22.750	21.750	22.438	1.840	8.201
TE	35.750	33.125	35.250	34.125	34.875	33.500	34.438	1.720	4.995
TNP	20.375	19.625	20.000	19.125	19.625	16.500	19.208	1.630	8.486
TXU	37.875	36.250	38.000	35.875	36.250	34.125	36.396	3.000	8.243
UCU	24.625	22.500	24.750	23.250	25.000	23.875	24.000	1.520	6.333
UEP	30.750	29.375	31.000	29.500	30.500	29.000	30.021	2.160	7.195
UIL	35.125	33.375	34.750	33.500	34.250	32.625	33.938	2.440	7.190
UTL	35.125	34.000	34.625	33.750	36.500	35.500	34.750	2.240	6.446
WEC	34.875	32.750	33.750	32.500	33.625	31.625	33.188	1.860	5.605
WPH	27.500	25.250	26.875	25.875	26.500	24.250	26.042	1.800	6.912
WPS	25.750	24.375	26.375	24.000	24.375	23.500	24.729	1.660	6.713
WWP	30.875	29.750	32.000	29.750	30.000	29.500	30.313	2.480	8.181

N=87.

[FR Doc. 91-17295 Filed 7-19-91; 8:45 am]
BILLING CODE 6717-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 906

Colorado Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule, approval of amendment.

SUMMARY: OSM is announcing its decision to approve a proposed amendment to the Colorado permanent regulatory program (hereinafter referred to as the Colorado program), as administered by the Colorado Mined Land Reclamation Division (MLRD) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment pertains to termination of jurisdiction, diversions, acid-forming and toxic-forming spoil, backfilling and grading, inspections, and individual civil penalties. The amendment revises the Colorado program to be consistent with SMCRA and the Federal regulations.

EFFECTIVE DATE: July 22, 1991.

FOR FURTHER INFORMATION CONTACT: Robert H. Hagen, Director, Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 625 Silver Avenue SW., suite 310, Albuquerque, NM 87102; telephone (505) 766-1486.

SUPPLEMENTARY INFORMATION:

I. Background

On December 15, 1980, the Secretary of the Interior conditionally approved the Colorado program as administered by MLRD. Information regarding the general background on the Colorado program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval can be found in the December 15, 1980, **Federal Register** (45 FR 82173). Actions concerning program amendments taken subsequent to the approval of the Colorado program are found at 30 CFR 906.15, 906.16, and 906.30.

II. Submission of Proposed Amendment

By letter dated April 11, 1991, Colorado submitted to OSM a proposed amendment to the rules of the Colorado Mined Land Reclamation Board at 2 Code of Colorado Regulations (CCR) 407-2 (Administrative Record No. CO-517). Colorado submitted the proposed amendment in response to the Director's previous deferral of a decision on a rule and in response to required program amendments at 30 CFR 906.16 (b), (c), (f), (g), and (h). This decision deferral and the required amendments are discussed in the final rule **Federal Register** notice (56 FR 1363, January 14, 1991; Administrative Record No. CO-514) for Colorado's July 18, 1989, proposed amendment.

In its April 11, 1991, amendment, Colorado proposed to delete or revise the following provisions of 2 CCR 407-2: Rule 3.03.3, termination of jurisdiction; Rules 4.05.3(1) (c), (d), and (e), diversions; Rule 4.05.8(1), acid-forming and toxic-forming spoil; Rule 4.05.9(2), temporary impoundments; Rule 4.14.1(1)(e), alternative backfilling and grading schedules; Rules 5.02.2 (8) and (9), inspections of abandoned sites; and Rule 5.04.7(1), individual civil penalties. OSM published a notice in the **Federal**

Register on May 2, 1991 (56 FR 20167), announcing receipt of the proposed amendment to the Colorado program and inviting public comment on its adequacy (Administrative Record No. CO–523).

By letter dated May 21, 1991 (Administrative Record No. CO–528), Colorado withdrew from OSM's consideration the proposed revision of Rule 4.05.9(2) regarding temporary impoundments.

The public comment period closed on June 3, 1991.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings for the proposed amendment submitted by Colorado on April 11, 1991.

1. Decision on the Rule for Which the Director Deferred His Decision in the January 14, 1991, Final Rule Federal Register Notice

The Director previously deferred his decision on Colorado's July 18, 1989, proposed termination of jurisdiction provisions at Rule 3.03.3 (1) and (2) (finding No. 9, 56 FR 1363, 1366, January 14, 1991; Administrative Record No. CO–514). The Director did so on the basis that he was pursuing an appeal of a U.S. District Court decision (*National Wildlife Federation* v. *Lujan*, 31 E.R.C. 2034, August 30, 1990) that remanded the Federal regulations at 30 CFR 700.11(d). In this April 11, 1991, amendment, Colorado proposes to delete Rule 3.03.3. Colorado's proposed deletion of termination of jurisdiction Rule 3.03.3 is consistent with the court's decision. Therefore, the Director approves the proposed deletion. Because Colorado proposes to delete Rule 3.03.3 and the Director approves this action, the Director's previous deferral decision is no longer applicable. If the Director prevails in his appeal of the court decision, he will notify Colorado of any needed regulatory change.

2. Decision on Rules for Which the Director Required Program Amendments in the January 14, 1991, Final Rule "Federal Register" Notice

Colorado proposes revisions to the following rules that are substantive in nature and contain language that is substantively identical to the corresponding Federal regulations, which in some instances have been modified by court decisions. Colorado submitted the proposed revisions in response to required program amendments at 30 CFR 906.16 (b), (c), (f), (g), and (h), which are discussed in the final rule Federal Register notice (finding Nos. 10, 11, 13, 15, and 16, 56 FR 1363, 1366 through 1369, January 14, 1991; Administrative Record No. CO–514) for Colorado's July 18, 1989, proposed amendment. Because the proposed revisions to these Colorado rules contain language that is substantively identical to the corresponding sections of the Federal regulations, as modified by court decisions, the Director finds that the following proposed revisions to the Colorado program are no less effective than the corresponding Federal regulations.

(a) Diversions, Rules 4.05.3(1) (c), (d), and (e)

The Director previously required at 30 CFR 906.16(b) that Colorado further amend Rule 4.05.3(1) to require that all diversions be located, constructed, maintained, and/or used to be stable, to provide protection against flooding and resultant damage to life and property, and to comply with applicable local, State, and Federal laws and regulations. Colorado proposes Rules 4.05.3(1) (c), (d), and (e) that are substantively identical to the corresponding Federal regulations at 30 CFR 816.43(a)(2) (i), (ii), and (iv). Therefore, the Director approves the proposed rules and removes the required amendment at 30 CFR 906.16(b).

(b) Acid-Forming and Toxic-Forming Spoil, Rule 4.05.8(1)

The Director previously required at 30 CFR 906.16(c) that Colorado further amend Rule 4.05.8(1) to require operators to identify, bury, and treat acid-forming and toxic-forming spoil and underground development waste where such spoil and waste may be detrimental to public health and safety. Colorado proposes Rule 4.05.8(1) that is substantively identical to the corresponding Federal regulations at 30 CFR 816.41(f)(1)(i) and 817.41(f)(1)(i). Therefore, the Director approves the proposed rule and removes the required amendment at 30 CFR 906.16(c).

(c) Alternative Backfilling and Grading Schedules, Rule 4.14.1(1)(e)

The Director previously required at 30 CFR 906.16(f) that Colorado remove Rule 4.14.1(1)(e) regarding Colorado's authority to approve alternative contemporaneous reclamation schedules. Colorado proposed deletion of Rule 4.14.1(1)(e) is consistent with 30 CFR 816.100, as modified by the U.S. District Court for the District of Columbia (*In re: Permanent Surface Mining Regulation Litigation (II), Rounds II and III*, No. 79–1144 (D.D.C. Oct. 1, 1984), 21 Env't Rep. Cas. 1724 and 620 F. Supp. 1519 (D.D.C. 1985, Mem. Op. at 52)). Therefore, the Director approves the proposed deletion of the rule and removes the required amendment at 30 CFR 906.16(f).

(d) Inspections of Abandoned Sites, Rules 5.02.2 (8) and (9)

The Director previously required at 30 CFR 906.16(g) that Colorado remove Rules 5.02.2 (8) and (9) regarding the definition and inspection of abandoned sites. Colorado's proposed deletion of Rules 5.02.2 (8) and (9) is consistent with 30 CFR 840.11 (g) and (h), as modified by the U.S. District Court for the District of Columbia (*National Wildlife Federation* v. *Lujan*, 31 E.R.C. 2034, August 30, 1990). Therefore, the Director approves the proposed deletion of the rule and removes the required amendment at 30 CFR 906.16(g).

(e) Individual Civil Penalties, Rule 5.04.7(1)

The Director previously required at 30 CFR 906.16(h) that Colorado further amend Rule 5.04.7(1) to remove the phrase "failure to abate." Colorado proposes Rule 5.04.7(1) that is substantively identical to the corresponding Federal regulation at 30 CFR 846.12(b). Therefore, the Director approves the proposed rule and removes the required amendment at 30 CFR 906.16(h).

IV. Summary and Disposition of Comments

Public Comments

The Director solicited public comment on the proposed amendment and provided opportunity for a public hearing. No comments were received, and the scheduled public hearing was not held because no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), OSM solicited comments from the Administrator of the Environmental Protection Agency (EPA), the Secretary of Agriculture, and various other Federal agencies with an actual or potential interest in the Colorado program.

By letter dated May 3, 1991 (Administrative Record No. CO–520), the U.S. Forest Service responded that it had no comments on and no objections to the proposed amendment.

By letter dated May 6, 1991 (Administrative Record No. CO–521), the U.S. Bureau of Mines responded that it had no comments.

By letter dated May 15, 1991 (Administrative Record No. CO–524), the U.S. Fish and Wildlife Service responded that it had no comments.

By letter dated May 15, 1991 (Administrative Record No. CO–526), the U.S. Bureau of Land Management responded that it had no comments.

By letter dated May 21, 1991 (Administrative Record No. CO–527), the U.S. Department of Agriculture, Soil Conservation Service (SCS), commented that it was concerned about "(1) diversions and conveyance design, location, construction maintained and used (2) temporary impoundment and (3) acid forming and toxic forming spoil and the handling of these waters and spoils [because] [t]here are no references to revegetative components."

As discussed in Section II of this notice, Colorado withdrew from OSM's consideration the proposed revision to Rule 4.05.9(2) regarding temporary impoundments. As discussed in finding No. 2, the Director is approving Colorado's proposed revision to Rules 4.05.3(1) (c), (d), and (e) regarding diversions and the proposed revisions to Rule 4.05.8(1) regarding acid-forming and toxic-forming spoil, because these rules are substantively identical to the corresponding Federal regulations. The Director is not, in response to SCS's comments, requiring Colorado to revise those rules to reference Colorado's revegetation rules, because the corresponding Federal regulations do not reference the Federal revegetation regulations.

By letter dated June 17, 1991 (Administrative Record No. CO–530), the Mine Safety and Health Administration (MSHA) responded that the proposed amendment did not appear to conflict with any current MSHA regulations.

State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP) Comments

Pursuant to 30 CFR 732.17(h)(4), the Director is required to solicit comments from SHPO and ACHP for all amendments that may have an effect on historic properties. Neither SHPO nor ACHP responded to OSM's request.

EPA Concurrence

Pursuant to 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of EPA with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*)

None of the changes that Colorado proposes to its rules pertain to air or water quality standards. Nevertheless, OSM requested EPA's concurrence on the proposed amendment (Administrative Record No. CO–518). By letter received May 17, 1991 (Administrative Record No. 525), EPA's Region VII office responded that it had no comments on the proposed amendment. By letter dated June 14, 1991 (Administrative Record No. CO–529), Washington DC office responded that it had no comments on the program amendment and concurred with it.

V. Director's Decision

Based on the above findings, the Director approves Colorado's program amendment as submitted on April 11, 1991. As discussed in finding Nos. 1 and 2, the Director has determined that the proposed deletion of Rule 3.03.3, termination of jurisdiction; revision of Rules 4.05.3(1) (c), (d), and (e), diversions); revision of Rule 4.05.8(1), acid-forming and toxic-forming spoil; deletion of Rule 4.14.1(1)(e), alternative backfilling and grading schedules; revision of Rules 5.02.2 (8) and (9), inspections of abandoned sites; and revision of Rule 5.04.7(1), individual civil penalties, are no less effective than the Federal regulations, as modified by court decisions. Therefore, he is removing the required program amendments at 30 CFR 904.16 (b), (c), (f), (g), and (h). The Director is approving the proposed rules with the provision that they be fully promulgated in identical form to the rules submitted to and reviewed by OSM and the public.

The Federal regulations at 30 CFR part 906 codifying decisions concerning the Colorado program are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

National Environmental Policy Act

The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

Executive Order 12291 and the Regulatory Flexibility Act

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Accordingly, for this action, OSM is exempt from the requirement to prepare a regulatory impact analysis, and this action does not require regulatory review by OMB. The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal regulations will be met by the State.

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by OMB under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 906

Intergovernmental relations, Surface mining, underground mining.

Dated: July 12, 1991.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T, the Code of Federal Regulations is amended as set forth below.

PART 906—COLORADO

1. The authority citation for part 906 continues to read as follows:

Authority: 30 U.S.C. 1201 et seq.

2. In § 906.15, a new paragraph (n) is added to read as follows:

§ 906.15 Approval of regulatory program amendments.

* * * * *

(n) The revisions to the following provisions of 2 CCR 407–2, the rules and regulations of the Colorado Mined Land Reclamation Board, as submitted on April 11, 1991, are approved on July 22, 1991. The amendment becomes effective upon State promulgation of the amendment in the same form as submitted to OSM.

Termination of jurisdiction—deletion of Rule 3.03.3; Diversions—Rules 4.05.3(1) (c), (d), and (e); Acid-forming and toxic-forming spoil—Rule 4.05.8(1); Alternative backfilling and grading schedules—deletion of Rule 4.14.1(1)(e);

Inspections of abandoned sites—deletion of Rules 5.02.2 (8) and (9); and

Individual civil penalties—Rule 5.04.7(1).

§ 906.16 [Amended]

3. Section 906.16 is amended by removing and reserving paragraphs (b) and (c), and by removing paragraphs (f), (g), and (h).

[FR Doc. 91-17274 Filed 7-19-91; 8:45 am]
BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 806b

[Air Force Regulation 12-35]

Air Force Privacy Act Program

AGENCY: Department of the Air Force, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is deleting one exemption rule to reflect changes made in accordance with the Privacy Act of 1974, as amended, (5 U.S.C. 552a).

EFFECTIVE DATE: July 22, 1991.

FOR FURTHER INFORMATION CONTACT: Mrs. Anne Turner, SAF/AAIA, The Pentagon, Washington, DC 20330-1000. Telephone (202) 697-3491 or Autovon 227-3491.

SUPPLEMENTARY INFORMATION: On June 11, 1991, at 56 FR 26800, the Department of the Air Force deleted a system of records identified as F053 AFA D, entitled Registrar Records. Therefore, the Air Force is now deleting the exemption rule for the system of records from the Air Force's exemption rules found at 32 CFR part 806b.

List of Subjects in 32 CFR Part 806b.

Privacy.

PART 806b—AIR FORCE PRIVACY ACT PROGRAM

For the reasons set forth in the preamble, 32 CFR part 806b is amended as follows:

1. The authority citation for 32 CFR part 806b is revised to read as follows:

Authority: Pub. L. 93-579, 88 Stat 1896 (5 U.S.C. 552a)

§ 806b.13 [Amended]

2. Section 806b.13 is amended by removing paragraphs (b)(19) (i), (ii), (iii), and redesignating paragraph (b)(20) as (b)(19).

Dated: July 17, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-17345 Filed 7-19-91; 8:45 am]
BILLING CODE 3810-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 88

[CGD 90-032]

RIN 2115-AD58

Inland Navigation Rules; Annex V: Pilot Rules

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The U.S. Coast Guard is designating light signals to identify vessels engaged in public safety activities. These regulations will enhance navigation safety by making these vessels easier to distinguish from other vessels.

EFFECTIVE DATE: August 21, 1991.

FOR FURTHER INFORMATION CONTACT: Mr. Harry C. Robertson, Short Range Aids to Navigation Division (G-NSR), (202) 267-0357.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Mr. Harry C. Robertson, Project Manager, and Lieutenant Ralph L. Hetzel, Project Counsel, Office of Chief Counsel.

Regulatory History

On July 18, 1990, the Coast Guard published a notice of proposed rulemaking entitled Inland Navigation Rules; Annex V; Pilot Rules in the **Federal Register** (55 FR 29229). The Coast Guard received 1067 letters commenting on the proposal. A public hearing was not requested and one was not held.

Background and Purpose

The Inland Navigational Rules Act of 1980 (33 U.S.C. 2001-2073) establishes navigation rules that apply to all vessels operating on the inland waters of the United States, and to vessels of the United States on the Canadian waters of the Great Lakes to the extent that there is no conflict with Canadian law. Annex V (Pilot Rules) to the Inland Navigation Rules provides for light displays in specific circumstances such as when required for law enforcement vessels, moored barges, and dredge pipelines.

For several years the Coast Guard has been considering the addition of a distinctive light signal to Annex V for identifying vessels engaged in public safety activities. The Navigation Safety Advisory Council and the National Boating Safety Advisory Council endorse the need for such an identification light signal. A distinctive light signal will permit easier and faster identification of vessels involved in public safety activities, especially when waterways are crowded or extra caution is required. It is intended neither to interfere with nor to take the place of other required lights.

The Coast Guard is establishing an alternately flashing red and yellow identification light signal for optional use by vessels engaged in public safety activities. Public safety activities are those which enhance safety on the water through either prevention or response. Examples are patrolling marine parades, regattas, or special water celebrations; traffic control; salvage; firefighting; medical assistance; assisting disabled vessels; and search and rescue.

Section 88.11 of the Pilot Rules allows law enforcement vessels to use a flashing blue light when engaged in direct law enforcement activities, but does not specifically authorize them to use it for public safety activities. Since the blue light is already installed on most law enforcement vessels it is more efficient to allow these vessels to use the blue light when performing public safety activities than to expect installation of another color light. Therefore, this rule also amends the Pilot Rules to permit law enforcement vessels to use the flashing blue light when engaged in public safety activities.

Discussion of Comments and Changes

One thousand sixty-seven written comments were received. No comment objected to law enforcement vessels using the blue light for public safety activities. Therefore, the following discussion deals only with the alternately flashing red and yellow identification light signal.

Thirty-four comments contained objections or suggested changes. The rest of the comments, most of which were written by Coast Guard Auxiliary members, favored the proposal completely. Many private boat owners commented with reports of close calls and casualties that might have been prevented by regatta patrols using an identification light signal. Several people commented that they had personally witnessed vessels cutting between a boat towing and a boat towed. They hoped that the identification light signal would prevent this by warning other vessels away.

A few comments objected that the red/yellow identification light signal would be confusing. To the contrary, the Coast Guard agrees with the majority of the comments that such a distinctive

light signal in a sea of boats at night would lessen confusion by warning that the vessel thus identified was engaged in a public safety activity.

A few others objected that the identification light signal would be abused. This is certainly possible, since some vessel operators engaged in exigent public safety activities might wrongly presume that their status gave them the right of way. The Coast Guard also knows that there is a problem with recreational boaters not recognizing or using towing lights and shapes. Also, many of those who commented incorrectly assumed that the identification light signal would take the place of, or at least take precedence over, the towing lights and shapes prescribed by the Inland Navigation Rules.

The Coast Guard's position is that the light signal in question serves only to identify vessels in the performance of public safety activities, and nothing else. It is definitely not a towing light. It does not grant the right of way. Its use does not relieve a vessel from the requirement to display the lights and shapes prescribed for the activity in which engaged, including towing.

The final rule has been drafted to clearly state that use of the light signal conveys no special privilege and that the Inland Navigation Rules must be followed. The Coast Guard will endeavor to educate the public and the user when publicizing the new regulation, and in any case will continue to enforce the Navigation Rules and the penalties for violating them.

Several suggestions were for different colored lights. Before issuing the NPRM, the Coast Guard considered other choices of color, and the red/yellow combination was the least likely to be mistaken for something else. All of the colors suggested: red, blue, yellow, blue/yellow, blue/red are already identified with some other function or are likely to be confused with something else. For example, blue lights can only be used by law enforcement vessels, and flashing red lights can be mistaken for aids to navigation.

The Coast Guard originally left the description of the light nonspecific so that the user might employ the most convenient system of manifesting the effect of an alternately flashing red and yellow light signal. However, comments showed that some guidance was necessary. The following paragraph describes the desired characteristics of the light signal, but does not restrict it to a device approved by the Coast Guard or other specified organization. If experience indicates that more restrictive action is necessary, it will be addressed in a future rulemaking.

It should be a standard police-type beacon, with a clear, weatherproof lens over a rotating pair of lights; one red and the other yellow. The red and yellow lights should meet the color specifications in Annex I of the Inland Navigation Rules. The lights should rotate between 70 and 100 revolutions per minute. The nominal range of visibility should be between one and three miles. The Coast Guard does not intend to institute a program of inspection and certification of these identification light signals. The user must be self-regulated and adhere to good judgement.

Twenty comments suggested that commercial salvage or towing vessels be allowed to use the identification light signal. The comments noted that due to recent Coast Guard policy, there has been a significant increase in commercial search and rescue (SAR). They pointed out that many commercial SAR cases occur at night or during busy holidays or major boating events, when a distinctive light signal would enhance the safety factor for this activity.

The Coast Guard agrees that since the main purpose of the new light signal is to make it obvious that there is a public safety activity in progress, then it would be illogical to exclude commercial salvors. Likewise, independent rescue services, emergency medical units, volunteer fire departments, and vessels affiliated with state or municipal governments should be allowed to use the identification light signal. Also, sponsors of regattas and marine events who have a permit from the Coast Guard are considered to be performing public safety activities.

Restrictive references to official public safety vessels have been removed from the final rule. However, it is not the Coast Guard's intent to open up use of the light signal to anyone who cares to use it. Only those activities sanctioned by government agencies or over which the Coast Guard has some measure of control can be considered public safety activities. Examples of these measures of control include the commercial towing endorsement, regatta permits and Auxiliary orders. It must be reiterated here that the light itself conveys no additional privilege, but serves only to identify a vessel as participating in public safety activities.

Regulatory Evaluation

This regulation is not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a Regulatory Evaluation is unnecessary. This rule does not impose any significant economic burden upon the public, as use of the new light is voluntary.

Small Entities

The rulemaking contains no burden on small entities, as the provisions of the rule are in response to public request, and are strictly voluntary. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612, and has determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2 of Commandant Instruction M16475.1B, this rulemaking is categorically excluded from further environmental documentation. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under "**ADDRESSES**".

List of Subjects in 33 CFR Part 88

Navigation (water), Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 88 as follows:

PART 88—[AMENDED]

1. The authority citation for part 88 is revised to read as follows:

Authority: 33 U.S.C. 2071; 49 CFR 1.46.

2. In § 88.11, paragraph (a) is revised to read as follows:

§ 88.11 Law enforcement vessels.

(a) Law enforcement vessels may display a flashing blue light when engaged in direct law enforcement or public safety activities. This light must be located so that it does not interfere

with the visibility of the vessel's navigation lights.

* * * * *

3. A new § 88.12 is added to read as follows:

§ 88.12 Public safety activities.

(a) Vessels engaged in government sanctioned public safety activities, and commercial vessels performing similar functions, may display an alternately flashing red and yellow light signal. This identification light signal must be located so that it does not interfere with the visibility of the vessel's navigation lights. The identification light signal may be used only as an identification signal and conveys no special privilege. Vessels using the identification light signal during public safety activities must abide by the Inland Navigation Rules, and must not presume that the light or the exigency gives them precedence or right of way.

(b) Public safety activities include but are not limited to patrolling marine parades, regattas, or special water celebrations; traffic control; salvage; firefighting; medical assistance; assisting disabled vessels; and search and rescue.

Dated: July 1, 1991.

J.W. Lockwood,

Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 91-17317 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-14-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 91-77; RM-7644]

Radio Broadcasting Services; Pentwater, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 231C3 for Channel 231A, Pentwater, Michigan, and modifies the construction permit for Station WSAB to specify operation on the higher class channel. This action is taken in response to a petition filed by C&S Broadcasting, Inc. See 56 FR 14054, April 5, 1991. Canadian concurrence has been obtained for this allotment at coordinates 43-46-38 and 86-26-25. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 30, 1991.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 91-77, adopted June 26, 1991, and released July 16, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, Downtown Copy Center, 1714 21st Street NW., Washington, DC 20036 (202) 452-1422.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Michigan, is amended by removing Channel 231A and adding Channel 231C3 at Pentwater.

Federal Communications Commission.

Andrew J. Rhodes,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 91-17278 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 89-449; RM-6802 and RM-7258]

FM Radio Broadcasting Services; Kings Beach, CA and Fallon, NV

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants the request of Kidd Communications, Inc., which holds a construction permit for a station at Kings Beach, California, to upgrade that station by substituting Channel 299C3 for present Channel 299A, pursuant to notice of proposed rule making, 54 FR 42523, October 17, 1989. The Commission also grants the counterproposal of Atrium Broadcasting Company by allotting Channel 267A to Fallon, Nevada as an additional FM broadcast service in that community. Channel 299C3 can be allotted to Kings Beach in compliance with the Commission's minimum interstation distance separation requirements using a site located at coordinates North Latitude 39-18-50 and West Longitude 119-53-00. Channel 267A can be allotted to Fallon in compliance with the Commission's minimum interstation distance separation requirements using a site located at coordinates North Latitude 39-28-24 and West Longitude 118-46-36. With this action, the proceeding is terminated.

EFFECTIVE DATE: August 30, 1991; the window period for filing applications for Channel 267A at Fallon, Nevada will open on September 3, 1991 and close on October 3, 1991.

FOR FURTHER INFORMATION CONTACT: J. Bertron Withers, Jr., Mass Media Bureau (202) 632-7792.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 89-449, adopted June 24, 1991 and released July 16, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center (202) 452-1422, 1714 21st Street NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 299A and adding Channel 299C3 at Kings Beach.

3. Section 73.202(b), the Table of FM Allotments under Nevada, is amended by adding Channel 267A at Fallon.

Federal Communications Commission.

Andrew J. Rhodes,

Chief, Allocations Branch, Policy & Rules Division, Mass Media Bureau.

[FR Doc. 91-17277 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 89-18; RM-6510, RM-6586, RM-6725]

Radio Broadcasting Services; Clinton, Saint Pauls, Southern Pines, NC, Chesterfield, SC

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of C. Curtis Sigmon, allots Channel 297A to Chesterfield, South Carolina, as the community's first local FM service. At the request of Muirfield Broadcasting, Inc., the Commission substitutes Channel 295C2 for Channel 296A at Southern Pines, North Carolina, modifies its license for Station WIOZ(FM) to specify operation on the higher powered channel, substitutes Channel 297A for Channel 295A at Saint Pauls, North Carolina, and orders Lumbee Regional Development Association, Inc., the applicant for the Saint Pauls channel to amend its application (BPH-880727MN) to specify the alternate Class A channel. The request of Sampson Broadcasting Co., Inc., to substitute Channel 295C2 for Channel 296A at Clinton, North Carolina, and modify its license for Station WCLN-FM to specify operation on the higher powered channel is denied. See 54 FR 7453, February 21, 1989. With this action, this proceeding is terminated.

DATES: Effective August 30, 1991. The window period for filing applications for Channel 297A at Chesterfield, South Carolina, will open on September 3, 1991, and close on October 3, 1991.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 89-18, adopted June 24, 1991, and released July 16, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

Channel 297A can be substituted for Channel 295A at Saint Pauls in compliance with the Commission's minimum distance separation requirements with a site restriction of 6.7 kilometers (4.2 miles) southeast, the site specified in Lumbee Regional Development Association, Inc.'s application. Channel 295C2 can be substituted for Channel 296A at Southern Pines in compliance with the Commission's minimum distance separation requirements with a site restriction of 7.9 kilometers (4.9 miles) west to accommodate Muirfield's desired transmitter site. Channel 297A can be allotted to Chesterfield in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 297A at Saint Pauls are North Latitude 34-42-59 and West Longitude 78-56-51. The coordinates for Channel 295C2 at Southern Pines are 35-09-04 and 79-28-40. The coordinates for Channel 297A at Chesterfield are 34-44-06 and 80-05-18.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the FM Table of Allotments under North Carolina is amended by removing Channel 295A and adding Channel 297A at Saint Pauls and by removing Channel 296A and adding Channel 295C2 at Southern Pines.

3. Section 73.202(b), the FM Table of Allotments under South Carolina, is amended by adding Chesterfield, Channel 297A.

Federal Communications Commission.

Andrew J. Rhodes,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 91-17279 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 90-649; Rm-7563]

Television Broadcasting Services; Roseburg, OR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of KMTR, Inc., allots Channel 46 to Roseburg, Oregon, as the community's third local commercial television channel. See 56 FR 1780, January 17, 1991. In addition, petitioner may amend its pending application for Channel 36 at Roseburg (BPH-900413KH) without loss of cut-off protection. Channel 46 can be allotted to Roseburg in compliance with the Commission's minimum distance separation requirements with a site restriction of 16.5 kilometers (10.3 miles) south to avoid the Portland "freeze" area. The coordinates for Channel 46 at Roseburg are 43-04-15 and West Longitude 123-23-18. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 30, 1991.

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 90-649, adopted June 25, 1991, and released July 16, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center (202) 452-1422, 1714 21st Street NW., Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Television broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.606 [Amended]

2. Section 73.606(b), the Table of TV Allotments under Oregon, is amended by adding Channel 46+ at Roseburg.

Federal Communications Commission.

Andrew J. Rhodes,

Cheif, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 91-17280 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 76

[MM Docket Nos. 90-4, 84-1296, FCC 91-184]

Cable Service; Effective Competition Standard for Cable Basic Service Rates

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This Report and Order modifies the Commission's rule that defines what constitutes "effective competition" to cable service. In the

absence of effective competition, a franchising authority is permitted to regulate basic cable service rates. The Report and Order also adopts new rules for the regulation of basic cable rates in such cases. In the Notice of Proposed Rule Making (55 FR 4208, February 7, 1990) and the Further Notice of Proposed Rule Making (56 FR 406, January 4, 1991), the Commission found that the existing three signal standard for determining whether a cable system is subject to effective competition no longer reflects the realities of the cable industry and the broader video marketplace. Under the new rules, effective competition would exist and local authority to regulate basic service rates would be preempted if either of the following conditions are met: (1) Six unduplicated over-the-air broadcast television signals are available in the entire cable community; or (2) an independently owned, competing multichannel video delivery service is available to 50 percent of the homes passed by the incumbent cable system and subscribed to by at least 10 percent of the homes passed by the alternative provider within the incumbent cable system's service area. The Report and Order also resolves related issues raised by the City of Dubuque, Iowa, in its petition for reconsideration of the existing rules adopted in MM Docket No. 84-1296. This action is part of a combined Report and Order and Second Further Notice of Proposed Rule Making that seeks additional comments on whether the elimination of signal carriage requirements for cable television systems since the Cable Act was enacted in 1984 undermines the effective competition.

EFFECTIVE DATES: October 25, 1991, pending approval by the Office of Management and Budget. A document announcing the effective date will be published in the Federal Register at a later date.

FOR FURTHER INFORMATION CONTACT: Marcia Glauberman, Mass Media Bureau, Policy and Rules Division, (202) 632-3410.

SUPPLEMENTARY INFORMATION: The following collection of information contained in these rules has been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act. Copies of the submission may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1114 21st Street NW., Washington, DC 20036. Persons wishing to comment on this information collection should direct their comments to Jonas Neihardt, (202) 395-4814, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503. A copy of any comments should also be sent to the Federal Communications Commission, Office of Managing Director, Washington, DC 20554. For further information contact Judy Boley, Federal Communications Commission, (202) 632-7513.

OMB Number: 3060-0416.
Title: Section 76.33, Standards for rate regulation.
Action: Revision.
Respondents: State or local governments, businesses (including small businesses).
Frequency Response: On occasion.
Estimated Annual Response: 32,100 responses; 17.63 hours per response; 566,000 hours total.

Needs and Uses: Section 76.33(a) requires documentation to be filed with the Commission by cable operators and franchising authorities which would enable the Commission to resolve disputes concerning the applicability of the signal availability standard. Section 76.33(b) requires the franchising authority to give formal notice to the public when establishing any rate for the provision of basic cable service by cable systems and to make a written statement when a decision on a rate matter is made. The formal notice is used by the public so that they may be provided an opportunity to make their views known at the local level on any rate provisions concerning cable service. The requirement for a written decision will ensure that local authorities are cognizant of and apply the standards for rate regulation required by the Commission.

This is a synopsis of the Commission's Report and Order in MM Docket Nos. 90-4 and 84-1296 adopted June 13, 1991, and released July 12, 1991. The complete text of this Report and Order is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1114 21st Street NW., Washington, DC.

Synopsis of Report and Order

1. Under the Cable Communications Policy Act of 1984 (Cable Act), in the absence of effective competition, a franchising authority has the discretion to regulate the rates charged for basic cable service. The Commission, in this Report and Order, modifies its rules to define the existence of "effective competition" for purposes of regulating basic cable service rates. For those cable systems whose basic service rates are regulated by their franchising authorities, the Commission will require that in setting or approving, rates, franchising authorities allow cable operators to earn a "fair return" on investment.

2. Section 623 of the Cable Act permits, but does not require, franchising authorities to regulate basic cable service rates only in those situations where the cable system is not subject to "effective competition." The Cable Act directed the Commission to define the circumstances in which a cable system is not subject to effective competition and to establish standards for the regulation of basic cable rates by local franchising authorities in such cases. In 1985, the Commission determined that the availability of three unduplicated over-the-air broadcast television signals is the appropriate test. The Cable Act also requires the Commission to periodically review its regulations, taking into account developments in technology. The Commission's Notice of Proposed Rule Making (Notice) initiating this proceeding was intended to review the rules regarding the regulation of basic cable service rates in light of changed circumstances in the video marketplace since the three signal standard was adopted. The resulting record led the Commission to believe that an effective competition standard based on three over-the-air broadcast signals no longer reflected the realities of the cable industry and the broader video marketplace. However, since the Notice did not seek comment on specific proposals, the Commission adopted a Further Notice of Proposed Rule Making (Further Notice) which proposed a multiple-option test for identifying effective competition. The Further Notice also requested comment on proposals to amend the standard for rate regulation by local franchising authorities in cable communities not subject to effective competition.

3. The Cable Act requires the Commission to look at competition for the limited purpose of determining in what situations rate regulation of basic cable service may take place. When the Commission adopted the three signal standard in 1985, the programming provided by basic cable service primarily consisted of retransmitted local, over-the-air broadcast television signals. Thus, the Commission concluded that a standard based on the reception of terrestrial television signals would provide a reasonable benchmark for determining the presence of effective competition for basic cable service. In

both the Notice and Further Notice, the Commission concluded that a review of the standard is appropriate because basic cable service had become more than the retransmission of local broadcast signals and often included a wide range of programming services. Since that time, press accounts report that some cable systems have reduced the size of their basic service package and moved some of the more costly program services to "expanded basic" tiers. Cable operators clearly have the general right to move individual cable services among tiers, and they may do so in their efforts to find the optimal mix of program services and prices. The programming services offering exclusive sports and other events not available over-the-air are those most likely to be removed from basic tiers as a result of high costs. That cable operators have the ability to remove such programming from the basic tier—and the evidence that many are doing so—reaffirms the Commission's view that a sufficient complement of over-the-air signals provides an acceptable competitive check on the ability of cable operators to raise their prices for basic cable service.

4. In the Further Notice, the Commission found that there are a number of ways to measure the presence or absence of effective competition because cable market power might derive from a variety of sources, the influence of which depends on local circumstances. In the Further Notice, the Commission proposed a multiple-option effective competition standard. Under the proposed standard, a cable system that met any of three criteria would be presumed to face effective competition and would be exempt from rate regulation by its franchising authority.

5. The first component of the proposed multiple-option effective competition standard is a signal/penetration test that would require that at least six unduplicated over-the-air broadcast signals be available in the cable community and that cable penetration be less than 50 percent. In the Report and Order, the Commission adopts only the six signal standard of the proposed test. the Commission's selection of a six over-the-air signal standard is intended to be conservative enough to ensure a complement of signals adequate to provide effective competition to the signal retransmission function of the basic tier, yet not so conservative as to cause unnecessary regulation.

6. With respect to determining the availability of over-the-air signals in the cable community, the Commission will generally continue to use the existing signal criteria to determine whether the six signal threshold has been met. Thus, a cable system will be deemed to face effective competition if at least six unduplicated broadcast television signals are available over the entire cable community, although the same six signals need not provide service to the entire community. The Commission will count all unduplicated over-the-air broadcast services available in the cable community including: Full service commercial stations, full service noncommercial stations, satellite stations, television translators and low power television stations. The *prima facie* standard of signal availability for full service stations will be based on predicted Grade B contours or significantly viewed status in the cable community. The *prima facie* standard of signal availability for television translator stations and low power stations will depend on their coverage areas based on their predicted protected contours.

7. The Commission initially recommended that a cable penetration criterion be considered along with the six signal complement to reflect the "antenna service" source of cable market power. After reviewing the record, the Commission has determined that no useful purpose would be served by subjecting additional cable systems to rate regulations where six signals are indeed available. The Commission finds that cable penetration is not a reliable indicator of either over-the-air signal quality or of cable market power. As commenters indicate, cable penetration is determined by a number of factors other than the quality of off-the-air signal reception. Commenters also point out numerous examples where basic cable rates do not vary directly with cable penetration levels.

8. In communities lacking six over-the-air signals, an incumbent cable system may also be subject to effective competition if another multichannel provider offers multiple channel options. Consequently, the second component of the proposed effective competition standard would consider the availability of a competing, independently-owned, multichannel video delivery service in the cable community. In order to determine whether the alternative video provider is sufficiently "available" in the cable community and whether consumers view it as a substitute for the incumbent cable system, the Commission proposed benchmarks of at least 50 percent availability and at least 10 percent penetration.

9. A significant majority of commenters support this proposal. The Commission adopts the multichannel test as proposed. The Commission believes that the following standards—50 percent availability among homes passed by the incumbent cable system and subscribed to by at least 10 percent of all homes passed by the alternative video delivery service within the incumbent cable system's service areas—are reasonable benchmarks for determining when a cable system faces effective competition from multichannel service providers. The Commission will consider providers of a competing cable service, a multichannel, multipoint distribution system (MMDS), satellite master antenna television (SMATV), home satellite dishes (HSD) and direct broadcast satellite services (DBS) as multichannel competitors for purposes of applying the multichannel competitor test because these alternatives provide a variety of programming services with many of the characteristics of local stations and provide for reception of local over-the-air stations.

10. Regarding the calculation of availability and penetration of alternative video delivery services, the Commission does not find it necessary to differentiate among alternative delivery services. To determine the availability of competing video services, the number of homes passed by at least one of these alternative delivery services should be totalled and expressed as a percentage of the number of homes passed by the incumbent cable system. Similarly, the penetration of alternative delivery services should be calculated by combining the number of subscribers to all available services and calculating the penetration on the basis of the homes passed by both an alternative provider and the incumbent cable system. The Commission also adopts the attribution criteria in § 76.50 of the rules to define an "independently-owned" multichannel competitor.

11. In the Further Notice, the Commission proposed a competitive behavior test that it believed could balance consumer interests in receiving cable service at reasonable rates and its desire to avoid unnecessary regulation in those situations where cable system rates have been restrained by market conditions. After analyzing the record, the Commission has decided not to include a competitive behavior test as a component of the effective competition standard. While it continues to believe that cable operators whose basic service rates appear to be competitively constrained should not be subject to

unnecessary regulation, the Commission finds that it would be difficult to establish benchmarks that would objectively measure whether a cable system is operating in a competitive manner. It is unlikely that there is a single competitive rate for any complement of cable service or one average per-channel price that consistently reflects competitive behavior because the cost of providing basic service differs among cable systems. The Commission concedes that it is not able to overcome the practical problems associated with establishing a competitive behavior test and, thus, will not adopt such a test.

12. In the Cable Act, Congress also required the Commission to establish standards applicable to regulation of basic cable service rates by local franchising authorities for cable systems not subject to effective competition as defined by the Commission. Currently, the Commision requires that any franchising authority exercising its right to establish rates for basic cable service: (1) give formal notice to the public; (2) provide an opportunity for interested parties to make their views known; and (3) make a formal statement, including a summary explanation, when a decision is made. In view of the substantive rates standards that the Commission is adopting in this Report and Order, these procedural standards are amended to explicitly require a written statement that explains any franchising authority decision on a cable rate matter. Any such statement need only set forth the factors considered and reasoning applied to the relevant issues that resulted in the decision, including those factors and issues included in the new substantive rate standards.

13. Under existing rules, local franchising authorities exercise discretion that is governed by the statute when determining the appropriate basic service rate for cable systems that do not face effective competition. In the Further Notice, the Commission proposed that franchising authorities apply a "fair return" standard when regulating basic cable rates. The evidence in the record indicates that substantive standards are needed to avoid recurrence of the past abuses of the rate-making power. Thus, the Commission adopts the "fair return" on investment standard that, in addition to a reasonable profit, will take into account capital, basic cable programming, customer service, labor and ancillary costs attributable to obtaining and retransmitting signals carried on the basic tier as well as changes in such costs and the cost of any requirements made by the franchising authority that do not relate directly to provision of cable service. The automatic five percent annual increase would apply before any franchising authority would become involved in rate regulation. Thereafter, these standards would govern all franchising authority rate determinations. However, the Commission does not adopt any particular rate-setting methodology to implement this standard, finding that reliance upon local communities to determine or approve specific rates is appropriate because each cable system operates under its own franchise agreement and is subject to different costs. This "fair return" on investment standard should simultaneously assist franchising authorities in determining the factors appropriate to consider when setting basic cable rates, preserve their control over the cable rates in their communities and assure them the flexibility to consider other relevant factors. Finally, the Commission adopts its proposal that disputes in applying this standard be directly appealable to the courts rather than to this Commission.

14. In the Further Notice, the Commission proposed to delegate to the franchising authority in the first instance the authority to determine whether a cable system meets the new effective competition standard, with direct review of such determinations by this Commission via the provision of § 76.33(c) of the rules. In addition, the Further Notice sought comment regarding standards for determining the presence of broadcast signals in conjunction with requests for waivers of the *prima facie* showing of the existence of effective competition.

15. The Commission will continue to delegate to the franchising authority the responsibility to determine whether a cable system meets the new effective competition standard. The Commission also will retain § 76.33 of the rules, which permits any party seeking to establish either the presence or absence of effective competition to petition the Commission in accordance with special relief provisions of § 76.7. Further, the Commission will retain the existing rules relating to the submission of engineering studies showing actual signal availability by parties seeking to rebut the predicted Grade B standard of signal availability for full service stations. The Commission clarifies the rules relating to the submission of engineering studies by parties seeking a waiver of the standard of signal availability for translators. Parties will now be required to submit engineering studies that show the actual protected contour of such signals, as defined in § 74.707 of the rules, using the methodology specified in § 73.686. These standards will also apply for low power television stations. However, the Commission has determined that it lacks authority to require one party to pay for the litigation-related expenses of another, and eliminates the existing rule regarding the reimbursement of the cost of engineering studies.

16. In the Notice, the Commission noted that any new rules it may adopt would likely authorize more franchising authorities to regulate the basic service rates of their local cable television systems. The Commission asked commenters to consider whether there was any action it could or should take that would prevent cable systems from engaging in strategic behavior (*e.g.*, raising rates or retiering) that would contravene the intent of any new rules during the time between adoption of new rules and their implementation. In the Report and Order, the Commission concludes that it lacks authority to roll back basic service rates that were increased by a cable system that faced effective competition under the rules that existed at the time of the increase. The Cable Act clearly specifies that rates may only be regulated when the cable system does not face effective competition as defined by the Commission. With respect to retiering, section 625 of the Cable Act explicitly and narrowly proscribes this Commission's and franchising authorities' ability to interfere in decisions by cable companies regarding unregulated tiers of service, which would include all tiers prior to institution of regulation. Thus, while the Commission recognizes that retiering in anticipation of regulation may affect the number of services offered on the basic tier, the Commission finds that the Cable Act clearly prevents any action by the Commission in this regard. Accordingly, no provisions regarding retiering prior to the imposition of rate regulation will be adopted.

17. In addition, the Report and Order resolves issues raised by the City of Dubuque, Iowa (Dubuque), in its petition for reconsideration of the Commission's Second Report and Order in MM Docket No. 84-1296, 53 FR 17049 (1988). In the Second Report and Order, the Commission modified the manner in which signal availability was measured in response to the decision in *American Civil Liberties Union* v. *FCC*, 823 F.2d 1554 (DC Cir. 1987), *cert. denied*, 108 S.Ct. 1220 (1988), which found, in part,

that the standard for measuring signal availability was arbitrary and capricious. In its petition for reconsideration, Dubuque argues that: (1) The audience surveys conducted to establish a signal's availability based on its significantly viewed status should be adjusted to reflect population densities; (2) the methodology specified for field strength measurements to determine actual signal availability in the cable community in waiver proceedings should taken into account population densities, not merely geographic areas; (3) procedures should be adopted to challenge a significant viewing survey (or waiver petition); and (4) the cost reimbursement rule should be modified to include legal costs as well as engineering costs.

18. In the Report and Order, the Commission rejects the revised methodology for significant viewing surveys proposed by Dubuque because it would inject a new, costly, burdensome and complicated element in the significant viewing standard that would not be needed in most instances in order to prepare a valid survey. The Commission also is not persuaded that it is necessary to modify the requirements of field strength studies to account for population densities throughout the cable community because a properly executed field strength study would rarely indicate that a signal is receivable in the cable community when, in fact, only a minority of the cable community's population can actually receive the signal. The Commission notes that the §§ 76.54(c) and 76.7(d) already permit interested parties to comment on any potential or actual problems associated with a significant viewing survey before it is undertaken or after a completed survey is submitted for review. Thus, no additional procedures are needed to challenge a significant viewing survey. Finally, since the Commission is eliminating its cost reimbursement rule in the Report and Order, the proposal to include legal fees is rejected. Accordingly, the Commission denies Dubuque's petition for reconsideration.

Final Regulatory Flexibility Statement

19. Pursuant to the Regulatory Flexibility Act of 1980, 5 U.S.C. 605, it is certified that this decision will have a significant impact on a substantial number of small entities because it will affect cable system operators by redefining effective competition, the basis for determining whether a system may be regulated by a local franchising authority.

20. The Secretary shall send a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act (Pub.L. No. 96-354, 94 Stat. 1164, 5 U.S.C. 601 et seq., (1981)).

21. Accordingly, *it is ordered* That pursuant to the authority contained in sections 4(i), 303 and 543(b)(3) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303 and 543(b)(3), part 76 of the Commission's rules, 47 CFR part 76, *is amended* as set forth below.

22. *It is ordered* That the rules set forth below will be effective October 25, 1991, pending approval by the Office of Management and Budget.

23. *It is further ordered* That the petition for reconsideration filed by the City of Dubuque, Iowa, is denied and the proceeding in MM Docket No. 84-1296 is terminated.

List of Subjects in 47 CFR Part 76

Cable television.

Amendatory text

Part 76 of chapter I of title 47 of the Code of Federal Regulations is amended to read as follows:

1. The authority citation for part 76 continues to read as follows:

Authority: 47 U.S.C. 154(i), 303 and 543(b)(3).

2. Section 76.33 is amended by revising paragraphs (a) and (b) to read as follows:

§ 76.33 Standards for rate regulation.

(a) A franchising authority is delegated the authority in the first instance to determine whether effective competition, as defined in this paragraph, exists in its community. When disputes arise regarding the franchising authority's initial determination, the presumption in a proceeding before the Commission will be that effective competition does not exist. A franchising authority may regulate the rates of a cable system subject to the following conditions (cable systems that were subject to rate regulation prior to this date will remain subject to that regulation pending demonstration that they may not be regulated pursuant to this section):

(1) Only basic cable service as defined in § 76.5(ii) may be regulated;

(2) Only cable systems that are not subject to effective competition may be rate regulated. A cable system will be determined to be subject to effective competition whenever any one of the following conditions are met:

(i) 100 percent of the cable community receives service from at least six unduplicated broadcast television signals. It is not necessary that the same six signals provide service to the entire community. Signals shall be counted on the basis of their predicted Grade B contour (as defined in § 73.683 of the rules) or if they are significantly viewed within the cable community, as defined in § 76.54 (b) and (c) of the rules. A signal that is significantly viewed shall be considered to be available to 100 percent of the cable community. A translator station is to be counted in the same manner as a full service station, except that its coverage area shall be based on its predicted protected contour as specified in § 74.707 of the rules, provided that the translator is not used to retransmit a station already providing a Grade B contour or significantly viewed signal within the cable community. A low power television station is to be counted in the same manner as a full service station, except that its coverage area shall be based on its predicted protected contour as specified in § 74.707 of the rules, provided it does not duplicate, as defined in the note below, another station counted in the same community.

Note: For purposes of this section, "duplicated broadcast television signal" is defined as one which does not simultaneously duplicate more than 50 percent of another signal's weekly prime time schedule pursuant to the definition of "prime time" provided in § 76.5(n).

(ii) An independently owned, multichannel video delivery service is available to at least 50 percent of the homes passed by the incumbent cable system (*i.e.*, the number of homes to which cable service is currently available whether or not a given household subscribes to cable service), and at least 10 percent of all homes passed by the alternative system within the incumbent cable system's service area actually subscribe to the service. Video delivery services that may be counted include a competing cable system, a multichannel, multipoint distribution system (MMDS), satellite master antenna television (SMATV), home satellite dishes (HSD), and direct broadcast satellite services (DBS). It is not necessary that the same multichannel video deliver service be available throughout the area. Availability of a competing multichannel video delivery system will be determined by dividing the number of homes passed by an alternative delivery service by the number of homes passed by the incumbent cable system and expressed as a percentage. The penetration of alternative video delivery services will be calculated by combining

the number of subscribers to all available services and expressing that number as a percentage of the homes passed by both an alternative provider and the incumbent cable system. Availability and penetration information for the competing multichannel video delivery services may be obtained from publicly available sources, from the operator directly, or from specifically undertaken audits. DBS will be considered to be available to the entire United States when any one such system service becomes operational.

Note: For purposes of this section, an MMDS service is considered to be "independently owned" if it meets the criteria contained in § 21.912 of the rules. The following services will be considered to be "independently owned" if cable system ownership (including all parties under common control) does not exceed the criteria contained in § 76.501 of the rules: SMATV, HSD, and DBS.

(3) The Commission may grant waivers of the effective competition standard where the filing party submits one or more of the following showings, as appropriate:

(i) The availability of full service broadcast signal(s) with engineering studies in accordance with § 73.686 of the Commission's rules or by other showings that such Grade B level signals are (or are not) in fact available within the community. In performing the engineering studies noted above, cluster measurements, as provided in § 73.686(b)(2)(viii) of this chapter, may be taken in place of mobile runs as provided in § 73.686(b)(2)(v) of this chapter. The availability of translator(s) or low power television station(s) with engineering studies in accordance with § 73.686 of this chapter or other showings that show the protected contour of such signals, as defined in § 74.707 of this chapter. In conducting these engineering studies, cluster measurements as provided in § 73.686(b)(2)(viii) of this chapter may be taken in place of the mobile runs as provided in § 73.686(b)(2)(v) of this chapter. Any party intending to obtain a study must first inform the other party and provide it an opportunity to negotiate a resolution.

(ii) The penetration of a competing cable system based on a survey of cable households passed and cable subscribers or more recent data;

(iii) The availability or penetration of alternative video delivery technologies specified in § 76.33(a)(2)(ii) with additional information, or relevant information with respect to alternative video delivery technologies not included in § 76.33(a)(2)(ii). The availability of MMDS may be demonstrated by a showing of its protected contour as specified in § 21.902 (d) and (e) of the rules.

(4) When a cable system not subject to effective competition becomes subject to effective competition due to any change in market conditions, the right of the local franchising authority to regulate the basic cable service rates of such cable system shall terminate immediately. A cable system, once determined to be subject to effective competition after the effective date of this section, shall not be subject to regulation for sixty days after any change in market conditions which would cause it to be determined not to be subject to effective competition. In instances where disputes arise between a cable system and a franchising authority regarding the changed circumstances, the status quo shall be maintained with respect to its regulatory status until the matter is resolved either by the parties or the Commission. However, if it is subsequently determined that the cable system does not face effective competition, the franchising authority may require the cable operator to rebate to subscribers the excess basic service rates charged during the pendency of appeal with interest, determined on the basis of the existing rate applicable to federal income tax refunds and payments, to compensate for the excess revenues collected when the cable system properly may have been regulated.

(5) Franchising authorities setting regulated basic cable service rates pursuant to this section shall allow a fair return on investment taking into account appropriate costs, including, but not necessarily limited to, capital costs, basic cable programming, customer service, labor, and ancillary costs attributable to obtaining and transmitting signals carried on the basic tier, increases in such costs, and the cost of any franchise-imposed requirements not directly related to the provision of cable service, as well as a reasonable profit. Franchising authorities shall presume the reasonableness of documented increases in those basic cable cost factors itemized in this "fair return on investment" standard. Franchising authorities shall retain the discretion to deny a proposed rate increase, but they shall be required to provide substantial written evidence supporting any decision to deny recovery of *bona fide*, documented increases in these itemized costs of providing basic cable service. Appeal of a franchising authority's decision shall be made to the state court with jurisdiction over such matters.

(b) In establishing any rate for the provision of basic cable service by cable systems subject to paragraph (a) of this section, the franchising authority shall:

(1) Give formal notice to the public;

(2) Provide an opportunity for interested parties to make their views known, at least through written submissions; and,

(3) Make a formal statement (including summary explanation) when a decision on a rate matter is made, and issue a written decision.

* * * * *

3. Section 76.54 is amended by revising paragraph (c) to read as follows:

§ 76.54 Significantly viewed signals; method to be followed for special showings.

* * * * *

(c) Notice of a survey to be made pursuant to paragraph (b) of this section shall be served on all licensees or permittees of television broadcast stations within whose predicted Grade B contour the cable community or communities are located, in whole or in part, and on all other system community units, franchisees, and franchise applicants in the cable community or communities at least (30) days prior to the initial survey period. Furthermore, if a survey is undertaken pursuant to the provisions of § 76.33(a)(2)(i) of the rules, notice shall also be served on the franchising authority. Such notice shall include the name of the survey organization and a description of the procedures to be used. Objections to survey organizations or procedures shall be served on the party sponsoring the survey within twenty (20) days after receipt of such notice.

* * * * *

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-17102 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

Proposed Rules

Federal Register
Vol. 56, No. 140
Monday, July 22, 1991

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 906

[Docket No. FV-91-410PR]

Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas; Proposed 1991-92 Expenses and Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule proposes authorizing expenditures for the 1991-92 fiscal period (August 1-July 31) for the Texas Valley Citrus Committee (TVCC), established under Marketing Order No. 906. This proposed action is needed by the TVCC to pay anticipated marketing order expenses. The proposed action would enable the TVCC to continue to perform its duties and the order to operate.

DATES: Comments must be received by August 1, 1991.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule to: Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525-S, Washington, DC 20090-6456. Three copies of all written material shall be submitted, and they will be made available for public inspection in the office of the Docket Clerk during regular business hours. All comments should reference the docket number and the date and page number of this issue of the Federal Register.

FOR FURTHER INFORMATION CONTACT: Gary D. Rasmussen, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525-S, Washington, DC 20090-6456, telephone 202-475-3918.

SUPPLEMENTARY INFORMATION: This proposed rule is issued under Marketing Agreement and Marketing Order No. 906, both as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. This agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the Act.

This rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are about 135 handlers subject to regulation under the marketing order for oranges and grapefruit grown in Texas, and about 2,500 orange and grapefruit producers in Texas. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of these handlers and producers may be classified as small entities.

The marketing order for Texas oranges and grapefruit, administered by the Department, requires that an annual budget of expenses be prepared by the TVCC and submitted to the Department for approval. The members of the TVCC are handlers and producers of Texas oranges and grapefruit. They are familiar with the TVCC's needs and with the costs for goods, services, and personnel in their local area and are thus in a position to formulate an appropriate budget. The budget is formulated and discussed in public meetings. Thus, all directly affected persons have an opportunity to participate and provide input.

The recommended budget is usually acted upon by the TVCC shortly before a season starts, or during the season when changes are needed, and expenses are incurred on a continuous basis. Therefore, budget approvals must be expedited so that the TVCC will have funds to pay its expenses.

The Texas Valley Citrus Committee (TVCC) met on June 18, 1991, and unanimously recommended a 1991-92 budget with expenditures of $102,250. Of this total, $46,000 is for administration of the marketing order and $56,250 is for administration of TexaSweet Citrus Advertising, Inc. (TCAI). TCAI has carried out the TVCC's advertising and promotion program for the past several seasons and plans limited public relations activities for 1991-92. Budgeted expenditures for 1990-91 were $107,810.

The TVCC's proposed 1991-92 expenditures are similar in size and scope to those of last fiscal year and are at a level needed to keep the marketing order functioning until Texas citrus production further recovers and increased supplies of fruit become available for the commercial market. The 1991-92 season Texas citrus crop is expected to be relatively small, due to long term damage to the citrus groves caused by a severe freeze in December of 1989. Due to the small expected crop, the TVCC recommended that no assessment rate be established for the 1991-92 fiscal year, the same recommendation it made last year for the 1990-91 season.

The TVCC plans to use funds from its reserve and an estimated $25,000 in interest income to finance its 1991-92 expenditures. The TVCC estimates that its reserve fund will amount to about $458,600 on July 31, 1991, which is more than adequate to cover the anticipated deficit.

Based on the foregoing, the Administrator of the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

A comment period of 10 days is deemed appropriate for this action. Since TVCC expenses are incurred on a continuous basis during the entire fiscal period, approval of the proposed expenditure authorization must be expedited.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements and orders, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, it is proposed that 7 CFR part 906 be amended as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

1. The authority citation for 7 CFR part 906 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. A new § 906.231 is added to read as follows:

§ 906.231 Expenses.

Expenses of $102,250 by the Texas Valley Citrus Committee are authorized for the fiscal period ending on July 31, 1992.

Dated: July 16, 1991.

William J. Doyle,

Associate Deputy Director, Fruit and Vegetable Division.

[FR Doc. 91–17362 Filed 7–19–91; 8:45 am]

BILLING CODE 3410–02–M

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7 CFR Part 927

[Docket No. FV–91–413 PR]

Proposed Expenses and Assessment Rate for Marketing Order Covering Winter Pears Grown in Oregon, Washington, and California

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would authorize expenditures and establish an assessment rate under Marketing Order 927 for the 1991–92 fiscal period (July 1–June 30). The proposal is needed for the Winter Pear Control Committee (committee) to incur operating expenses during the 1991–92 fiscal year and to collect funds during that year to pay those expenses. This would facilitate program operations. Funds to administer this program are derived from assessments on handlers.

DATES: Comments must be received by August 1, 1991.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Patrick Packnett, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456, telephone 202–475–3862.

SUPPLEMENTARY INFORMATION: This rule is proposed under Marketing Agreement and Marketing Order No. 927 (7 CFR part 927) regulating the handling of winter pears grown in Oregon, Washington, and California. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

This proposed rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

Approximately 90 handlers of winter pears are subject to regulation under this marketing order each season. There are approximately 1,800 winter pear producers in Washington, Oregon, and California. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of the handlers and producers of winter pears may be classified as small entities.

The winter pear marketing order, administered by the Department, requires that the assessment rate for a particular fiscal year shall apply to all assessable pears handled from the beginning of such year. An annual budget of expenses is prepared by the committee and submitted to the Department for approval. The members of the committee are handlers and producers of winter pears. They are familiar with the committee's needs and with the costs for goods, services, and personnel in their local area and are thus in a position to formulate appropriate budgets. The budgets are formulated and discussed in public meetings. Thus, all directly affected persons have an opportunity to participate and provide input.

The assessment rate recommended by the committee is derived by dividing anticipated expenses by expected shipments of pears (in standard boxes or equivalents). Because that rate is applied to actual shipments, it must be established at a rate which will produce sufficient income to pay the committee's expected expenses. Recommended budgets and rates of assessment are usually acted upon by the committee shortly before a season starts, and expenses are incurred on a continuous basis. Therefore, budget and assessment rate approvals must be expedited so that the committee will have funds to pay its expenses.

The committee met on May 31, 1991, and unanimously recommended 1991–92 fiscal year expenditures of $5,130,616 and an assessment rate of $0.38 per standard box, or equivalent, of assessable pears shipped under M.O. 927. In comparison, 1990–91 fiscal year budgeted expenditures were $4,943,738 and the assessment rate was $0.315.

Major expenditure items this year in comparison to 1990–91 budgeted expenditures (in parentheses) are $4,305,000 ($3,859,775) for paid advertising, $128,176 ($317,767) for contingencies to cover unanticipated expenses, and $246,000 ($350,861) for research designed to improve winter pear yields and quality. The committee has budgeted $145,000 for industry development, of which $100,000 would be held in reserve for use in the event of any consumer related industry crisis. The balance of $45,000 would cover consultant services provided by the Northwest Horticultural Council. The remaining expenses are primarily for program administration and are budgeted at about last year's amounts.

Assessment income for the 1991–92 fiscal year is expected to total $4,674,000 based on shipments of 12,300,000 packed boxes of pears. Other available funds, including $32,408 in prior year

assessments, $30,000 in miscellaneous income, and a reserve of $394,208 carried into this fiscal year, would also be utilized to cover the proposed 1991–92 fiscal year expenditures. The committee's reserves are within authorized limits.

While this proposed action would impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be significantly offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

Based on the foregoing, it is found and determined that a comment period of 10 days is appropriate because the budget and assessment rate approval for the pear program needs to be expedited and the committee needs to have sufficient funds to pay its expenses, which are incurred on a continuous basis.

List of Subjects in 7 CFR Part 927

Marketing agreements, Reporting and recordkeeping requirements, Winter pears.

For the reasons set forth in the preamble, it is proposed that 7 CFR part 927 be amended as follows:

PART 927—WINTER PEARS GROWN IN OREGON, WASHINGTON, AND CALIFORNIA

1. The authority citation for 7 CFR part 927 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. New § 927.231 is added to read as follows:

§ 927.231 Expenses and assessment rate.

Expenses of $5,130,616 by the Winter Pear Control Committee are authorized, and an assessment rate of $0.38 per standard box, or equivalent, of pears is established for the fiscal year ending June 30, 1992. Unexpended funds from the 1991–92 fiscal year may be carried over as a reserve.

Dated: July 16, 1991.

William J. Doyle,

Associate Deputy Director, Fruit and Vegetable Division.

[FR Doc. 91–17363 Filed 7–19–91; 8:45 am]

BILLING CODE 3410–02–M

7 CFR Parts 1001, 1002, 1004, 1005, 1007, 1011, 1030, 1033, 1036, 1040, 1044, 1046, 1049, 1065, 1068, 1079, 1093, 1094, 1096, 1097, 1098, 1099, 1106, 1108, 1120, 1124, 1126, 1131, 1132, 1135, 1138

[Docket No. AO–14–A65, etc; DA–91–013]

Milk in the New England and Other Marketing Areas; Notice of Hearing on Proposed Amendments to Tentative Marketing Agreement and Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of public hearing on proposed rulemaking.

7 CFR Part	Marketing Area	AO Nos.
1001	New England	AO–14–A65
1002	New York-New Jersey.	AO–71–A80
1004	Middle Atlantic	AO–160–A68
1005	Carolina	AO–388–A5
1007	Georgia	AO–366–A34
1011	Tennessee Valley	AO–251–A36
1030	Chicago Regional	AO–361–A29
1033	Ohio Valley	AO–166–A62
1036	Eastern Ohio-Western Pennsylvania.	AO–179–A57
1040	Southern Michigan	AO–225–A43
1044	Michigan Upper Peninsula.	AO–299–A27
1046	Louisville-Lexington-Evansville.	AO–123–A63
1049	Indiana	AO–319–A40
1065	Nebraska-Western Iowa.	AO–86–A48
1068	Upper Midwest	AO–178–A46
1079	Iowa	AO–295–A42
1093	Alabama-West Florida.	AO–386–A12
1094	New Orleans-Mississippi.	AO–103–A54
1096	Greater Louisiana	AO–257–A41
1097	Memphis, Tennessee.	AO–219–A47
1098	Nashville, Tennessee.	AO–184–A56
1099	Paducah, Kentucky	AO–183–A46
1106	Southwest Plains	AO–210–A53
1108	Central Arkansas	AO–243–A44
1120	Lubbock-Plainview, Texas.	AO–328–A31
1124	Pacific Northwest	AO–368–A20
1126	Texas	AO–231–A61
1131	Central Arizona	AO–271–A30
1132	Texas Panhandle	AO–262–A41
1135	Southwestern Idaho-Eastern Oregon.	AO–380–A10
1138	Rio Grande Valley	AO–335–A37

SUMMARY: This hearing is being held to consider a proposal to amend 31 Federal milk marketing orders. The proposal would establish a separate classification and product formula price for milk used to produce butter and nonfat dry milk. The hearing was requested by 12 cooperative associations that represent a substantial number of dairy farmers who supply these markets. The cooperative associations maintain that the current and projected market value of milk used to produce butter and nonfat dry milk is less than the basic formula price, the Minnesota-Wisconsin price for manufacturing grade milk, which is the current price of such milk. They contend that this difference in the values of milk will increase substantially and create a financial hardship on dairy farmers whose milk is used to produce butter and nonfat dry milk. The cooperative associations have requested that this issue be handled on an emergency basis.

DATES: The hearing will convene at 9 a.m. local time on July 30, 1991.

ADDRESSES: The hearing will be held at the Ramada Hotel—Old Town, 901 N. Fairfax Street, Alexandria, Virginia 22314, (703) 683–6000.

FOR FURTHER INFORMATION CONTACT: John F. Borovies, Marketing Specialist, USDA/AMS/Dairy Division, Order Formulation Branch, room 2968, South Building, P.O. Box 96456, Washington, DC 20090–6456.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12291.

Notice is hereby given of a public hearing to be held at the Ramada Hotel—Old Town, 901 N. Fairfax Street, Alexandria, Virginia 22314, beginning at 9 a.m., on July 30, 1991, with respect to proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the aforesaid marketing areas.

The hearing is called pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR part 900).

The purpose of the hearing is to receive evidence with respect to the economic and marketing conditions which relate to the proposed amendments, hereinafter set forth, and any appropriate modifications thereof, to the tentative marketing agreements and to the orders.

Evidence also will be taken to determine whether emergency marketing conditions exist that would warrant omission of a recommended decision under the rules of practice and procedure (7 CFR 900.12(d)) with respect to proposal No. 1.

Actions under the Federal milk order program are subject to the Regulatory Flexibility Act (Pub. L. 96–354). This Act seeks to ensure that, within the statutory

authority of a program, the regulatory and information requirements are tailored to the size and nature of small businesses. For the purposes of the Act, a dairy farm is a "small business" if it has an annual gross revenue of less than $500,000, and a dairy products manufacturer is a "small business" if it has fewer than 500 employees. Most parties subject to a milk order are considered as a small business. Accordingly, interested parties are invited to present evidence on the probable regulatory and informational impact of the hearing proposals on small businesses. Also, parties may suggest modifications of these proposals for the purpose of tailoring their applicability to small businesses.

Interested parties who wish to introduce exhibits should provide the Presiding Officer at the hearing with 6 copies of such exhibits for the Official Record. Also, it would be helpful if additional copies are available for the use of other participants at the hearing.

The authority citation for 7 CFR parts 1001, 1002, 1004, 1005, 1007, 1011, 1030, 1033, 1036, 1040, 1044, 1046, 1049, 1065, 1068, 1079, 1093, 1094, 1096, 1097, 1098, 1099, 1106, 1108, 1120, 1124, 1126, 1131, 1132, 1135, 1138 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

The proposed amendments, as set forth below, have not received the approval of the Secretary of Agriculture.

Proposed by Atlantic Dairy Cooperative, Agri-Mark, Associated Milk Producers, Inc., Darigold Farms, Dairymen's Creamery Association, Inc., Dairymen, Inc. Independent Cooperative Milk Producers Association, Maryland and Virginia Milk Producers, Michigan Milk Producers Association, Milk Marketing, Inc., United Dairymen of Arizona, and Wisconsin Dairies:

Proposal No. 1

Revise Class III Price, § .50(c) in most of the aforesaid order, to read as follows:

The Class III price shall be the basic formula price for the month, except for producer milk used to produce butter and nonfat dry milk and condensed milk product in bulk fluid form used to produce butter and nonfat dry milk, which will be a separate Class III–a price computed pursuant to paragraphs (c) (1) through (3) of this section.

(c)(1) Multiply the butter price pursuant to § .74 by 4.2;

(c)(2) Multiply by 8.2 the nonfat dry milk price for the month, where the nonfat dry milk price means the simple average of the prices per pound of nonfat dry milk for the Central States production area as published by the Dairy Division, Agricultural Marketing Service.

(c)(3) From the sum of paragraphs (c)(1) and (c)(2), subtract the appropriate Commodity Credit Corporation manufacturing allowance for converting 100 pounds of whole milk into butter and nonfat dry milk powder, $1.22, and round to the nearest cent.

Proposed by the Dairy Division, Agricultural Marketing Service:

Proposal No. 2

Make such changes as may be necessary to make the entire marketing agreements and the orders conform with any amendments thereto that may result from this hearing.

Copies by this notice of hearing and the orders may be procured from the Market Administrator of each of the aforesaid marketing areas, or from the Hearing Clerk, room 1083, South Building, United States Department of Agriculture, Washington, DC 20250, or may be inspected there.

Copies of the transcript of testimony taken at the hearing will not be available for distribution through the Hearing Clerk's Office. If you wish to purchase a copy, arrangements may be made with the reporter at the hearing.

From the time that a hearing notice is issued and until the issuance of a final decision in a proceeding, Department employees involved in the decisional process are prohibited from discussing the merits of the hearing issues on an ex parte basis with any person having an interest in the proceeding. For this particular proceeding, the prohibition applies to employees in the following organizational units:

Office of the Secretary of Agriculture
Office of the Administrator, Agricultural Marketing Service
Office of the General Counsel
Dairy Division, Agricultural Marketing Service (Washington office only)
Office of the Market Administrator of the aforesaid Marketing Areas

Procedural matters are not subject to the above prohibition and may be discussed at any time.

Signed at Washington, DC on: July 16, 1991.

Daniel D. Haley,

Administrator.

[FR Doc. 91–17361 Filed 7–19–91; 8:45 am]

BILLING CODE 3410–02–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91–NM–129–AD]

Airworthiness Directives; Airbus Industrie Model A300, A310, and A300–600 Series Airplane

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD), applicable to certain Airbus Industrie Model A300, A310, and A300–600 series airplanes, which would require a one-time visual inspection of BF Goodrich slides and slide raft lanyard assemblies, and replacement of release pin lanyards, if necessary. This proposal is prompted by recent reports of breakage of a release pin lanyard, an unauthorized modification of a release pin assembly, and incorrect installation of release pins. These conditions, if not corrected, could result in non-deployment of the emergency evacuation slides and/or slide rafts during an emergency evacuation.

DATES: Comments must be received no later than September 9, 1991.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM–103, Attention: Airworthiness Rules Docket No. 91–NM–129–AD, 1601 Lind Avenue SW., Renton, Washington 98055–4056. The applicable service information may be obtained from Airbus Industrie, Airbus Support Division, Avenue Didier Daurat, 31700 Blagnac, France. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Holt, Standardization Branch, ANM–113; telephone (206) 227–2140. Mailing address: FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rule Docket number and be submitted in duplicate to the

address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA/public contact, concerned with the substance of this proposal, will be filed in the Rules Docket.

Commenter wishing the FAA to acknowledge receipt of their comments submitted in response to this Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 91-NM-129-AD." The post card will be date/time stamped and returned to the commenter.

Discussion

The Direction Générale de l'Aviation Civile (DGAC) which is the airworthiness authority of France, in accordance with existing provisions of a bilateral airworthiness agreement, has notified the FAA of an unsafe condition which may exist on all Airbus Industrie Model A300, A310, and A300-600 series airplanes equipped with BF Goodrich emergency evacuation slides and/or slide rafts. There have been recent reports of breakage of a release pin lanyard due to corrosion of the split roll pin that was used as a guide pin on early configuration release pins, an unauthorized modification of a release pin assembly, and incorrect installation of release pins. These conditions, if not corrected, could result in non-deployment of the emergency evacuation slides and/or slide rafts during an emergency evacuation.

Airbus Industrie has issued Service Bulletins A300-25-434 (for Model A300 series airplanes), A300-25-6028 (for Model A300-600 series airplanes), and A310-25-2054 (for Model A310 series airplanes), all dated October 22, 1990, which describe procedures to perform a one-time visual inspection of BF Goodrich slide and slide raft lanyard assemblies for stop pins in the early configuration, unauthorized modifications, incorrect installation and operation, and damage to lanyard cables; and replacement of release pin lanyards, if necessary. The French DGAC has classified these service bulletins as mandatory, and has issued Airworthiness Directive 90-215-119(B) addressing this subject. The FAA has reviewed and approved BF Goodrich Service Bulletin 25-230, dated July 20, 1990, which is referenced in the aforementioned Airbus service bulletins.

This airplane model is manufactured in France and type certificated in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on other airplanes of the same type design registered in the United States, an AD is proposed which would require a one-time visual inspection of BF Goodrich slides and slide raft lanyard assemblies for stop pins in the early configuration, unauthorized modifications, incorrect installation and operation, and damage to lanyard cables; and replacement of release pin lanyards, if necessary, in accordance with the Airbus service bulletins previously described.

It is estimated that 113 airplanes of U.S. registry would be affected by this AD, that it would take approximately 1 manhour per airplane to accomplish the required actions, and that the average labor cost would be $55 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $6,215.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291, (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket No. 91-NM-129-AD.

Applicability: Model A300, A310, and A300-600 series airplanes equipped with BF Goodrich emergency evacuation slides and/or slide rafts, certificated in any category.

Compliance: Required as indicated, unless previously accomplished.

To prevent non-deployment of the emergency evacuation slides and/or slide rafts during an emergency evacuation, accomplish the following:

(a) Within 120 days after the effective date of this AD, accomplish the following in accordance with Airbus Service Bulletins A300-25-434 (for Model A300 series airplanes), A300-25-6028 (for Model A300-600 series airplanes), and A310-25-2054 (for Model A310 series airplanes), all dated October 22, 1990, as applicable:

Note: These service bulletins reference BF Goodrich Service Bulletin 25-230, dated July 20, 1990, for additional instructions.

(1) Perform a visual inspection of release pin lanyard assemblies for release pins in the early configuration, unauthorized modifications, and incorrect installation and operation. Prior to further flight, replace release pin lanyards in the early configuration, unauthorized modifications, or incorrectly installed or damaged release pin lanyards, if found.

(2) Perform a visual inspection of lanyard cables for evidence of fraying. If frayed lanyards are found, replace the lanyards prior to further flight.

(b) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer

may obtain copies upon request to Airbus Industrie, Airbus Support Division, Avenue Didier Daurat, 31700 Blagnac, France. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington.

Issued in Renton, Washington, on July 8, 1991.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-17331 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Kentucky Permanent Regulatory Program; Regulatory Reform, Fish and Wildlife Resources, Revegetation, and Regulations Changes From 1990 General Assembly Legislation

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of a proposed program amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of proposed modifications to Kentucky Administrative Regulations (KAR) at 405 KAR 7:015 documents incorporated by reference; 405 KAR 7:020 definitions; 405 KAR 7:030 applicability; 405 KAR 7:035 exemption for coal extraction incidental to the extraction of other minerals; 405 KAR 7:080 small operator assistance; 405 KAR 8:010 general provisions for permits; 405 KAR 8:020 coal exploration; 405 KAR 8:030 surface coal mining permits; 405 KAR 8:040 underground coal mining permits; 405 KAR 10:200 Kentucky bond pool; 405 KAR 16:180 and 405 KAR 18:180 protection of fish, wildlife, and related environmental values; 405 KAR 16:190 and 405 KAR 18:190 backfilling and grading; 405 KAR 16:200 and 405 KAR 18:200 revegetation; 405 KAR 16:210 and 18:220 postmining land use capability; 405 KAR 20:010 coal exploration; Technical Reclamation Memorandums (TRM) No. 19 field sampling techniques for determining ground cover, productivity, and stocking success of reclaimed surface mined lands; and TRM No. 20 methodologies for the evaluation, protection and enhancement of fish and wildlife resources for coal mining and reclamation operations. The proposed amendment is in response to four of OSM's 732 letters, changes in the Surface Mining Control and Reclamation Act (SMCRA), the 1990 Kentucky General Assembly legislative changes, and several grammatical corrections.

This notice sets forth the times and locations that the Kentucky program and the proposed amendment are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding a public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on August 21, 1991. If requested, a public hearing on the proposed amendment will be held at 10 a.m. on August 16, 1991. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on August 6, 1991.

ADDRESSES: Written comments and requests for a hearing should be mailed or hand delivered to: William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 340 Legion Drive, suite 28, Lexington, Kentucky 40504. Copies of the Kentucky program, the proposed amendment, and all written comments received in response to this notice will be available for review at the addresses listed below, Monday through Friday, 9 a.m. to 4 p.m., excluding holidays. Each requestor may receive, free of charge, one copy of the proposed amendment by contacting OSM's Lexington Field Office.

Office of Surface Mining Reclamation and Enforcement, Lexington Field Office, 340 Legion Drive, Suite 28, Lexington, Kentucky 40504, telephone: (606) 233-7327.

Office of Surface Mining Reclamation and Enforcement, Eastern Support Center, Ten Parkway Center, Pittsburgh, Pennsylvania 15220, telephone: (412) 937-2828.

Department for Surface Mining Reclamation and Enforcement, No. 2 Hudson Hollow Complex, Frankfort, Kentucky 40601, telephone: (502) 564-6940.

If a public hearing is held, its location will be: The Harley Hotel, 2143 North Broadway, Lexington, Kentucky 40505.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, telephone: (606) 233-7327.

SUPPLEMENTARY INFORMATION:

I. Background

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404-21435). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 917.11, 917.15, 917.16, and 917.17.

II. Discussion of Amendment

By letter dated November 19, 1990, (Administrative Record No. KY-1016) the Director, OSM notified Kentucky that the State regulations must be amended to be consistent with revised Federal regulations. In response to the Director's November 19, 1990 letter, Kentucky submitted, on June 28, 1991, (Administrative Record No. KY-1059) a proposed program amendment modifying 19 regulations and incorporating two Technical Reclamation Memorandum No. 19 and 20. In part the proposed amendment is in response to four outstanding OSM 30 CFR part 732 letters dated February 22, 1985 (Administrative Record No. KY-622), August 22, 1988 (Administrative Record No. KY-822), February 7, 1990 (Administrative Record No. KY-969) and February 8, 1990 (Administrative Record No. KY-967) and Director Harry M. Snyder's letter of November 19, 1990 to Secretary Carl H. Bradley. These proposed regulation changes correspond to changes in the federal regulations pertaining to fish and wildlife resources, revegetation, postmining land use, coal exploration, individual civil penalties, and the 16⅔ exemption for coal extraction incidental to the extraction of other minerals.

The proposed amendment also contains three changes as identified at 30 CFR 917.16(d) and discussed in the **Federal Register** dated December 31, 1990 (55 FR 53490-53510). The proposed amendment contains a new definition for a small operator that corresponds to the Public Law 95-87 change in definition. The proposed amendment also includes changes resulting from the Kentucky 1990 General Assembly legislation. These proposed changes are to the definition of surface coal mining and reclamation operations from 250 tons to 25 tons mined, the Kentucky

bond pool, and incidental boundary revisions.

Finally, a new category of revision was created called an "operator change revision". The proposed regulation establishes permitting procedure at 405 KAR 8:010 section 20 to revise permits when an operator change occurs on a specific mine site. Additionally, the proposed amendment contains several grammatical corrections throughout for clarity and proper citation.

The proposed amendment would amend the following Kentucky Administrative Regulations (KAR).

KAR Title 405 Chapter 7—General Provisions for KAR Title 405 Chapters 8 through 24

405 KAR 7:015 Documents incorporated by reference
405 KAR 7:020 Definitions of terms used in 405 KAR chapters 7 through 24
405 KAR 7:030 Applicability
405 KAR 7:035 Exemption for coal extraction incidental to the extraction of other minerals
405 KAR 7:080 Small operator assistance

KAR Title 405 Chapter 8 Permits

405 KAR 8:010 General provisions for permits
405 KAR 8:020 Coal exploration
405 KAR 8:030 Surface coal mining permits
405 KAR 8:040 Underground coal mining permits

KAR Title 405 Chapter 10 Bond and Insurance Requirements

405 KAR 10:200 Kentucky bond pool

KAR Title 405 Chapter 16 Performance Standards for Surface Mining Activities

405 KAR 16:180 Protection of fish, wildlife, and related environmental values
405 KAR 16:190 Backfilling and grading
405 KAR 16:200 Revegetation
405 KAR 16:210 Postmining land use capability

KAR Title 405 Chapter 18 Performance Standards for Underground Mining Activities

405 KAR 18:180 Protection of fish, wildlife, and related environmental values
405 KAR 18:190 Backfilling and grading
405 KAR 18:200 Revegetation
405 KAR 18:220 Postmining land use capability

KAR Title 405 Chapter 20 Special Performance Standards

405 KAR 20:010 Coal exploration

The proposed amendment also incorporates Technical Reclamation Memorandums (TRM) No. 19 field sampling techniques for determining ground cover, productivity, and stocking success of reclaimed surface mined lands; and TRM No. 20 methodologies for the evaluation, protection and enhancement of fish and wildlife resources for coal mining and reclamation operations

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Kentucky satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kentucky program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commentor's recommendations. Comments received after the time indicated under "**DATES**" or at locations other than the Lexington Field Office will necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by 4 p.m. on August 6, 1991. If no one requests an opportunity to comment at a public hearing, the hearing will not be held. Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendments may request a meeting at the OSM, Lexington Field Office listed under "**ADDRESSES**" by contacting the person listed under "**FOR FURTHER INFORMATION CONTACT.**" All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed under "**ADDRESSES.**" a written summary of each meeting will be made a part of the Administrative Record.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 15, 1991.

Carl C. Close,

Assistant Director, Eastern Support Center.

[FR Doc. 91-17291 Filed 7-19-91; 8:45 am]
BILLING CODE 4310-05-M

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30 CFR Part 948

West Virginia Permanent Regulatory Program, Civil Penalty Requirements

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the West Virginia permanent regulatory program (hereinafter referred to as the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment contains revisions to the State's Surface Mining Reclamation Regulations (title 38, series 2) which were partially approved by the Secretary of the Interior in the **Federal Register** on May 23, 1990 (55 FR 21304-21340). Specifically, this amendment contains revisions to the State's civil penalty assessment procedures as set forth in section 20, subsections 20.5 through 20.7 of the State's regulations.

This notice sets forth the times and locations that the West Virginia program and the proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on August 21, 1991. If requested, a public hearing on the proposed amendments will be held at 1 p.m. on August 12, 1991. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on August 6, 1991.

ADDRESSES: Written comments should be mailed or hand delivered to the Office of Surface Mining Reclamation

and Enforcement, Charleston Field Office, attention: West Virginia Administrative Record, 603 Morris Street, Charleston, West Virginia 25301

Copies of the proposed amendment (Administrative Record No. WV 866), the West Virginia program, and the administrative record on the West Virginia program are available for public review and copying at the OSM office and the office of the State regulatory authority listed below, Monday through Friday, 9 a.m. to 4 p.m., excluding holidays.

Office of Surface Mining Reclamation and Enforcement, Charleston Field Office, 603 Morris Street, Charleston, West Virginia 25301, telephone: (304) 347–7158

West Virginia Division of Energy, 1615 Washington Street, East, Charleston, West Virginia 25311, telephone (304) 348–3500.

In addition, copies of the proposed amendment are available for inspection during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Morgantown Area Office, 75 High Street, room 229, Morgantown, West Virginia 26505, telephone: (304) 291–4004.

Office of Surface Mining Reclamation and Enforcement, Beckley Area Office, 101 Harper Park Drive, Beckley, West Virginia 25801, telephone (304) 255–5265.

Each requester may receive one free copy of the proposed amendment by contacting the OSM Charleston Field Office.

FOR FURTHER INFORMATION CONTACT: Mr. James C. Blankenship, Jr., Director, Charleston Field Office; Office of Surface Mining Reclamation and Enforcement; 603 Morris Street; Charleston, West Virginia 25301; telephone (304) 347–7158.

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program

On January 21, 1981, the Secretary of the Interior conditionally approved the West Virginia program. Information concerning the general background of the permanent program submission, as well as the Secretary's findings, the disposition of comments and an explanation of the initial conditions of the approval of the West Virginia program can be found in the January 21, 1981, **Federal Register** (46 FR 5915–5956). Subsequent actions concerning the West Virginia program and previous amendments are codified at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Discussion of Proposed Amendment

By letter dated July 12, 1991 (Administrative Record No. WV 866), the West Virginia Division of Energy (WVDOE) submitted an amendment to its approved permanent regulatory program pursuant to 30 CFR 732.17. This amendment contains revisions to the State's civil penalty assessment procedures as set forth in subsections 20.5 through 20.7 of the West Virginia Surface Mining Reclamation Regulations. The State's regulations were partially approved by the Secretary of the Interior on May 23, 1990 (55 FR 21304–21340).

In its letter of July 12, 1991, the WVDOE advised OSM that the proposed amendment contains civil penalty provisions that are identical to those that were submitted on May 1, 1991 (Administrative Record No. WV 865). Because of unexpected delays in processing the May 1, 1991, amendment and to expedite their approval, the WVDOE requested that the provisions of subsections 20.5 through 20.7 be withdrawn from the earlier amendment and processed separately.

The proposed amendment contains revisions to the State's regulations at paragraph (b) of subsection 20.5 requiring that each imminent harm cessation order be initially assessed in accordance with the assessment rates set forth in subsection 20.7. West Virginia's approved program provides that no mandatory civil penalty be assessed for imminent harm cessation orders that are abated or expire within twenty-four hours.

As proposed, paragraph (a) of subsection 20.6 provides that, in addition to requiring an inspection of the violation prior to assessment, the findings of that inspection must be submitted to the assessment officer in writing. Paragraph (a) also provides the assessment officer the authority to continue conferences, conduct investigations, and interview witnesses as necessary.

Paragraph (c) of subsection 20.6 contains proposed requirements governing the servicing of civil penalty assessments by mail. In addition, the revised paragraph provides the circumstances under which failure by the Commissioner to serve a proposed assessment would be grounds for dismissal.

Proposed paragraph (d) of subsection 20.6 allows any person, other than the operator and WVDOE representatives, to submit in writing at the time of the conference a request to present evidence concerning the violations. The proposed paragraph also provides that, should scheduling problems arise, the assessment officer can continue the conference to a later time or date.

The informal conference procedures that are proposed in paragraph (e) of subsection 20.6 have been revised to incorporate the proposed changes mentioned above in paragraphs (c) and (d). In addition, so as to be consistent, all references to conference officer have been changed to assessment officer.

Proposed paragraph (k) of subsection 20.6 provides that inability to comply may no longer be considered in establishing a time period for suspending a permit. However, it may still be considered in mitigating the amount of a civil penalty.

The proposed amendment contains significant changes in the State's civil penalty rates and the criteria that is taken into consideration when assessing civil penalties. Proposed revisions to subsection 20.7 include: Increasing the penalty rate for history of violations; clarifying that a violation which initially has a seriousness rating of seven or higher is an imminent harm violation and thereby requires a cessation order to be issued; adjusting the civil penalty rates for seriousness and negligence; clarifying what constitutes operator negligence; modifying the penalty rate for good faith by not including history of violations in the amount and assessing it on a percentage basis; and clarifying the circumstances under which good faith is to be awarded.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comments on the proposed amendment submitted by the State of West Virginia to its permanent regulatory program. Specifically, OSM is seeking comments on the revisions to the State's Surface Mining Reclamation Regulations, title 38, series 2, that were submitted on July 12, 1991 (Administrative Record No. WV 866). Comments should address whether the proposed amendment satisfies the applicable criteria of 30 CFR 732.15. If deemed adequate, the amendment will become part of the West Virginia permanent regulatory program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking and include

explanations in support of the commenter's recommendations. Comments received after the time indicated under "**DATES**" or at locations other than the OSM Charleston Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by the close of business on August 6, 1991. If no one has requested an opportunity to participate in the hearing by that date, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate remarks and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one person requests to comment at a hearing, a public meeting, rather than a public hearing, may be held and the results of the meeting included in the Administrative Record.

Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the OSM Charleston Field Office listed under "**ADDRESSES**" by contacting the person listed under "**FOR FURTHER INFORMATION CONTACT**".

All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed under "**ADDRESSES**". A written summary of each public meeting will be made a part of the Administrative Record.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 15, 1991.

Carl C. Close,

Assistant Director, Eastern Support Center.

[FR Doc. 91-17292 Filed 7-19-91; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 22

[FRL-3974-5]

Rules of Practice Governing the Administrative Assessment of Civil Penalties Under the Clean Air Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is today proposing a rule to establish procedures for the administrative assessment of civil penalties under sections 113(d)(1) and 205(c) of the Clean Air Act (CAA), 42 U.S.C. 7413(d)(1) and 7524(c), as amended by the Clean Air Act Amendments of 1990, Public Law 101-549. The proposed rule provides that EPA's administrative assessment of civil penalties pursuant to section 113(d)(1) and section 205(c) will be governed by EPA's Consolidated Rules of Practice for assessing administrative penalties, 40 CFR part 22, and by supplemental rules relating specifically to the section 113(d)(1) and section 205(c) administrative procedures.

EPA is taking this action in response to the enactment of the Clean Air Act Amendments of 1990, which authorize the Administrator to assess administrative penalties for specified violations of the CAA. The section 113(d)(1) penalty assessments are applicable to non-title II violations while section 205(c) penalty assessments relate to title II violations. Section 205(c) authorizes the administrative assessment of civil penalties prescribed in sections 205(a), 211(d), and 213(d) of the Act, 42 U.S.C. 7524(a), 7545(d), and 7547(d). Section 211(d) similarly authorizes the administrative assessment of civil penalties, with the administrative penalties to be assessed in accordance with section 205(c). The authority granted to the Administrator to assess the administrative penalties was immediately effective upon the enactment of the Clean Air Act Amendments of 1990, on November 15, 1990.

Today's proposal does not concern and should not be confused with the field citation program authorized by section 113(d)(3) of the CAA. EPA will be proposing rules for the field citation program in a separate rulemaking at a future date.

DATES: Comments on the proposed rule must be submitted on or before August 21, 1991.

ADDRESSES: Interested parties may submit written comments (in duplicate if possible) to Public Docket No. A-91-37. It is requested that a duplicate copy be submitted to Scott A. Throwe at the address in the "For Further Information" section below. The docket is located at the Air Docket, room M-1500, Waterside Mall, United States Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket may be inspected between 8:30 am and 12 noon and between 1:30 pm and 3:30 pm on weekdays. As provided by 40 CFR part 2, a reasonable fee may be charged for photocopying docket materials.

FOR FURTHER INFORMATION CONTACT: Scott A. Throwe, Office of Air and Radiation, Stationary Source Compliance Division (EN-341W), United States Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; telephone (703) 308-8699.

SUPPLEMENTARY INFORMATION: On November 15, 1990, the Clean Air Act Amendments of 1990 (CAA Amendments), Public Law 101-549, was enacted. Section 701 of the CAA Amendments amended section 113 of the CAA, 42 U.S.C. 7413, by, among other things, providing the Administrator the authority to administratively assess penalties for a wide variety of violations of the CAA, excluding violations of title II of the Act. The Administrator may assess a penalty of up to $25,000 per day of violation, and may seek up to a maximum total penalty of $200,000, for violations where the first alleged date of violation occurred no more than 12 months prior to the initiation of the administrative penalty action. Both the amount of the maximum penalty sought and the length of the period of alleged violation may be increased by a joint determination of the Administrator and the Attorney General.

Section 228 of the CAA Amendments amended section 205 of the CAA, 42 U.S.C. 7524, by, among other things, providing the Administrator the authority to administratively assess penalties for certain violations of title II of the CAA. The Administrator may assess an administrative penalty of up to $25,000 per day for violations of sections 203(a)(2) and 211(d) of the CAA, up to $25,000 per offense for violations of paragraphs (1), (3)(A), (4) and (5) of section 203(a) and for violations of section 213(d), and up to $2,500 per offense for violations of section 203(a)(3)(B) and for violations of section 203(a)(3)(A) by any person other than a manufacturer or dealer. As with section 113(d), the maximum amount

that can be sought against each violator in an administrative assessment is $200,000. There is no corresponding limit relating to the first alleged date of the violation. The amount of maximum penalty sought may be increased by a joint determination of the Administrator and the Attorney General.

The CAA Amendments explicitly make section 113(d)(1) and section 205(c) penalty assessments subject to an opportunity for a hearing in accordance with sections 554 and 556 of the Administrative Procedure Act (APA), 5 U.S.C. 554, 556. EPA's Consolidated Rules of Practice ("Consolidated Rules" or "CROP"), 40 CFR part 22, govern the administrative assessment of civil penalties under other statutes administered by EPA that are subject to these requirements of the APA. By providing a common set of procedural rules for certain of EPA's administrative penalty programs, the Consolidated Rules reduce paperwork, inconsistency, and the burden on the person regulated. See 45 FR 24360 (Apr. 9, 1980). Various supplementary rules have been promulgated to implement provisions for specific statutes. 40 CFR part 22 subpart H.

EPA proposes that the Consolidated Rules be used as the procedural framework for administrative penalty assessments under section 113(d)(1) and section 205(c) of the CAA. Use of the Consolidated Rules allows EPA to implement the administrative penalty authority with uniform hearing procedures that satisfy the procedural and substantive requirements established by the CAA. The use of the Consolidated Rules, together with the proposed Supplemental rules discussed below, will satisfy the hearing procedures and discovery requirements of sections 113(d)(2)(a) and 205(c)(1). In particular, the requirement to have reasonable rules of discovery is met by the discovery provisions in 40 CFR 22.19. The statutory notice requirement is satisfied by 40 CFR 22.13, which requires EPA to initiate civil penalty proceedings by the issuance of a complaint against the person alleged to have violated the CAA. Furthermore, 40 CFR 22.14(a)(6) requires that the complaint include a notice of the respondent's right to request a hearing on any material fact alleged in the complaint, or on the appropriateness of the proposed penalty. Taken together, the Consolidated Rules will also meet the requirements of sections 554 and 556 of the APA. Accordingly, EPA is today proposing a rule which provides that the Consolidated Rules shall govern adjudicatory proceedings for the assessment of civil administrative penalties under section 113(d)(1) and section 205(c) of the CAA.

In conjunction with the use of the general Consolidated Rules (CROP §§ 22.01 through 22.32), EPA is proposing Supplemental rules that will apply specifically to section 113(d)(1) and section 205(c) penalty assessments. In particular, EPA is proposing a new Supplemental rule, CROP § 22.42, which will contain supplemental rules of practice for administrative penalty hearings under CAA section 113(d)(1). EPA also is proposing to amend CROP § 22.34, which will contain the supplemental practice rules for administrative penalty hearings under CAA section 205(c). Thus, CROP § 22.42 will provide supplemental practice rules for CAA administrative penalty hearings other than those under title II, whereas CROP § 22.34 will provide supplemental rules for title II hearings.

The two proposed Supplemental rules include a provision for a 30 day written notice of the proposed order, and provisions for administrative subpoenas based on the new administrative subpoena authority in section 703 of the CAA Amendments, which amended CAA section 307(a), 42 U.S.C. 7607(a). Virtually identical subpoena provisions appear in several other CROP Supplemental rules. In addition, several provisions of Supplemental rule 22.34 have been deleted in order to conform it more closely to new Supplemental rule 22.42.

The Consolidated Rules currently provide that penalty assessments under former section 211(d) of the Clean Air Act, 42 U.S C. 7545(d), are subject to those Rules. See 40 CFR 22.01(a)(2) and 22.34. Section 211(d), as revised by the CAA Amendments, provides that the penalties prescribed in section 211(d) are to be assessed in accordance with section 205(c). Today's proposal revises 40 CFR 22.01(a)(2) and 22.34 and adds a new § 22.42 to reflect that these rules of practice are to govern all adjudicatory proceedings for the administrative assessment of civil penalties under sections 113(d)(1), 205(c), 211(d) and 213(d) of the CAA.

EPA requests comments on all of the above matters.

EPA has determined that an expedited comment period of thirty (30) days should be used for this proposed rule. EPA has long-standing regulations on formal adjudicatory hearings for civil penalty assessments under several other environmental statutes. These regulations, the Consolidated Rules of Practice, were promulgated after notice and opportunity to comment and have been successfully used by the Agency for over a decade. Today's proposal adopts these well-established rules for all penalty proceedings under section 113(d)(1) and section 205(c). The statute-specific Supplemental rules proposed today do little more than codify statutory provisions. EPA therefore believes that the thirty day period provided for comment on this proposed rule is appropriate.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 through 612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment, a regulatory flexibility analysis which describes the impact of the rule on small entities (i.e., small businesses, small organizations and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant impact on a substantial number of small entities. In such circumstances, a regulatory flexibility analysis is not required.

The expected impact of the rule on small entities is negligible. The rule codifies already existing statutory provisions and is procedural. Thus, it does not impose additional regulatory requirements on small entities.

Accordingly, I hereby certify that these regulations will not have a significant impact on a substantial number of small entities. These regulations, therefore, do not require a regulatory flexibility analysis.

Executive Order No. 12291

Under Executive Order 12291, the Agency must judge whether a regulation is "major" and thus subject to the requirement to prepare a Regulatory Impact Analysis. The proposed rule published today is not major because the rule will not result in an effect on the economy of $100 million or more, will not result in increased costs or prices, will not have significant adverse effects on competition, employment, investment, productivity, and innovation, and will not significantly disrupt domestic or export markets. Therefore the Agency has not prepared a Regulatory Impact Analysis under the Executive Order.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order No. 12291.

Paperwork Reduction Act

These proposed rules do not contain any information collection requirements

subject to OMB review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.).

List of Subjects in 40 CFR Part 22

Administrative practice and procedures, Clean Air Act, Environmental protection, Penalties.

Dated: July 8, 1991.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, 40 CFR part 22 is proposed to be amended as follows:

PART 22—[AMENDED]

1. The authority citation for part 22 is revised to read as follows:

Authority: 15 U.S.C. 2615; 42 U.S.C. 7413(d), 7524(c), 7545(d), 7547(d), 7601 and 7607(a); 7 U.S.C. 136(l) and (m); 33 U.S.C. 1319, 1415 and 1418; 42 U.S.C. 6912, 6928 and 6991(e); 42 U.S.C. 9609; 42 U.S.C. 11045.

2. Section 22.01 is amended by revising paragraph (a)(2) to read as follows:

§ 22.01 Scope of these rules.

(a) * * *

(2) The assessment of any administrative penalty under sections 113(d)(l), 205(c), 211(d) and 213(d) of the Clean Air Act, as amended (CAA) (42 U.S.C. 7413(d)(1), 7524(c), 7545(d) and 7547(d)).

* * * * *

3. Section 22.34 is revised to read as follows:

§ 22.34 Supplemental rules of practice governing the administrative assessment of civil penalties under title II of the Clean Air Act.

(a) *Scope of these Supplemental rules.* These Supplemental rules shall govern, in conjunction with the preceding Consolidated Rules of Practice (40 CFR part 22), all proceedings to assess a civil penalty conducted under sections 205(c), 211(d), and 213(d) of the Clean Air Act, as amended (42 U.S.C. 7524(c), 7545(d), and 7547(d)). Where inconsistencies exist between these Supplemental rules and the Consolidated Rules (§§ 22.01 through 22.32), these Supplemental rules shall apply.

(b) *Issuance of Notice.* (1) Prior to the issuance of an administrative penalty order assessing a civil penalty, the person to whom the order is to be issued shall be given written notice of the proposed issuance of the order. Such notice shall be provided by the issuance of a complaint pursuant to § 22.13 of the Consolidated Rules of Practice.

(2) Notwithstanding § 22.15(a), any answer to the complaint must be filed with the Hearing Clerk within thirty (30) days after service of the complaint.

(c) *Subpoenas.* (1) The attendance of witnesses or the production of documentary evidence may be required by subpoena. The Presiding Officer may grant a request for a subpoena upon a showing of:

(i) The grounds and necessity therefor, and

(ii) The materiality and relevancy of the evidence to be adduced. Requests for the production of documents shall describe with specificity the documents sought.

(2) Subpoenas shall be served in accordance with § 22.05(b)(1) of the Consolidated Rules of Practice.

(3) Witnesses summoned before the Presiding Officer shall be paid the same fees and mileage that are paid in the courts of the United States. Fees shall be paid by the party at whose instance the witness appears. Where a witness appears pursuant to a request initiated by the Presiding Officer, fees shall be paid by EPA.

4. Add a new section 22.43 to read as follows:

§ 22.43 Supplemental rules of practice governing the administrative assessment of civil penalties under section 113(d)(1) of the Clean Air Act.

(a) *Scope of these Supplemental rules.* These Supplemental rules shall govern, in conjunction with the preceding Consolidated Rules of Practice (40 CFR part 22), all proceedings to assess a civil penalty conducted under section 113(d)(1) of the Clean Air Act (42 U.S.C. 7413(d)(1)). Where inconsistencies exist between these Supplemental rules and the Consolidated Rules (§§ 22.01 through 22.32), these Supplemental rules shall apply.

(b) *Issuance of Notice.* (1) Prior to the issuance of an administrative penalty order assessing a civil penalty, the person to whom the order is to be issued shall be given written notice of the proposed issuance of the order. Such notice shall be provided by the issuance of a complaint pursuant to § 22.13 of the Consolidated Rules of Practice.

(2) Notwithstanding § 22.15(a), any answer to the complaint must be filed with the Regional Hearing Clerk within thirty (30) days after service of the complaint.

(c) *Subpoenas.* (1) The attendance of witnesses or the production of documentary evidence may be required by subpoena. The Presiding Officer may grant a request for a subpoena upon a showing of:

(i) The grounds and necessity therefor, and

(ii) The materiality and relevancy of the evidence to be adduced. Requests for the production of documents shall describe with specificity the documents sought.

(2) Subpoenas shall be served in accordance with § 22.05(b)(1) of the Consolidated Rules of Practice.

(3) Witnesses summoned before the Presiding Officer shall be paid the same fees and mileage that are paid in the courts of the United States. Fees shall be paid by the party at whose instance the witness appears. Where a witness appears pursuant to a request initiated by the Presiding Officer, fees shall be paid by EPA.

[FR Doc. 91-17237 Filed 7-19-91; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Parts 417, 431, 434, and 1003

RIN 0991-AA44

Medicare and State Health Care Programs: Fraud and Abuse; Civil Monetary Penalties and Intermediate Sanctions for Certain Violations by Health Maintenance Organizations and Competitive Medical Plans

AGENCY: Office of the Secretary, Office of Inspector General (OIG) and the Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement sections 9312(c)(2), 9312(f), and 9434(b) of Public Law 99-509, the Omnibus Budget Reconciliation Act of 1986; section 7 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987; section 4014 of Public Law 100-203, the Omnibus Budget Reconciliation Act of 1987; sections 224 and 411(k)(12) of Public Law 100-360, the Medicare Catastrophic Coverage Act of 1988; and section 6411(d)(3) of Public Law 101-239, the Omnibus Budget Reconciliation Act of 1989. These provisions broaden the Secretary's authority to impose intermediate sanctions and civil monetary penalties on health maintenance organizations (HMOs) and other prepaid health plans contracting under Medicare or Medicaid that (1) substantially fail to provide an enrolled individual with required medically necessary items and services; (2) engage in certain marketing, enrollment, reporting, or claims payment abuses; or

(3) in the case of Medicare, employ or contract with, either directly or indirectly, an individual or entity excluded from participation in Medicare. The provisions also condition Federal financial participation (FFP) in certain State payments on the State's exclusion of certain entities excluded (or excludable) from Medicare. This rulemaking is intended to significantly enhance the protections for Medicare beneficiaries and Medicaid recipients enrolled in a HMO, CMP, or other contracting organization under titles XVIII and XIX of the Social Security Act.

DATES: To assure consideration, comments must be mailed and delivered to the address provided below by September 20, 1991.

ADDRESSES: Address comments in writing to: Office of Inspector General, Department of Health and Human Services, Attention: LLR-10-P, room 5246, 330 Independence Avenue, SW., Washington, DC 20201.

If you prefer, you may deliver your comments to room 5551, 330 Independence Avenue SW., Washington, DC. In commenting, please refer to file code LLR-10-P. Comments received timely will be available for public inspection, beginning approximately two weeks after publication, in Room 5551, 330 Independence Avenue SW., Washington, DC on Monday through Friday of each week from 9 a.m. to 5 p.m., (202) 619-3270.

FOR FURTHER INFORMATION CONTACT:

Zeno W. St. Cyr, II, Legislation, Regulations, and Public Affairs Staff, OIG, (202) 619-3270

or

Jean D. LeMasurier, Office of Prepaid Health Care, HCFA, (202) 619-2070

or

Ann Page, Medicaid Bureau, HCFA, (301) 966-5364.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Prepaid health plans, such as health maintenance organizations (HMOs), competitive medical plans (CMPs), and health insuring organizations (HIOs) are entities that provide enrollees with comprehensive, coordinated health care in a cost-efficient manner. Payment for these plans is generally made on a prepaid, capitation basis. The goal of prepaid health care delivery is to control health care costs while at the same time providing enrollees with affordable, coordinated, quality health care services. Titles XVIII and XIX of the Social Security Act (the Act) authorize contracts with prepaid health plans for the provision of covered health services to Medicare beneficiaries and Medicaid recipients.

B. Medicare

Section 1876 of the Act provides for Medicare payment at predetermined rates to eligible organizations that have entered into risk contracts with HFCA, or for payment of reasonable costs to eligible organizations that have entered into cost contracts. Eligible organizations include HMOs that have been federally qualified under title XIII, section 1310(d) of the Public Health Service Act, and CMPs that meet the requirements of section 1876(b)(2) of the Act.

Medicare enrollees of organizations with risk contracts are required to receive covered services only through the organization, except for emergency services and urgently needed out-of-area services. In the case of a cost contract, the Medicare beneficiary may also receive services outside the organization, with Medicare paying for the services through the general Medicare fee-for-service system. If an HMO or CMP fails to comply with a contract provision, the Secretary may decide not to renew or to terminate the contract. Regulations governing non-renewal of a contract are found at 42 CFR 417.492, and regulations governing termination of a contract are at 42 CFR 417.494.

C. Medicaid

Section 1903(m) of the Act contains requirements that apply to State Medicaid contracts for the provision, on a risk basis, either directly or through arrangements, of at least certain specified services ("comprehensive services"). HCFA regulations at 42 CFR part 434 implement the requirements in section 1903(m), and contain other requirements applicable to Medicaid contracts generally. Section 434.70 provides that HCFA may withhold Federal matching payments, known as Federal financial participation (FFP), for State expenditures for services provided to Medicaid recipients when either party to a contract substantially fails to carry out the terms of the contract.

D. New Legislation

1. The Omnibus Budget Reconciliation Act of 1986

Section 9312(c)(2) of Public Law 99-509, the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), added section 1876(f)(3) of the Act. This provision authorizes the Secretary to suspend enrollment of Medicare beneficiaries by an organization, or to suspend payment to the organization for individuals newly enrolled, after the date the Secretary notifies the organization of noncompliance with the requirement in section 1876(f)(1) that limits enrollment to no more than 50 percent Medicare beneficiaries and Medicaid recipients. Prior to OBRA 86, HCFA's only recourse against an organization for noncompliance with any contract provisions was to non-renew or initiate termination of the contract. The new authority provides alternative remedies that may be used in lieu of or in addition to contract non-renewal or termination for organizations that do not comply with the 50/50 enrollment composition requirement.

Additionally, sections 9312(f) and 9434(c) of OBRA 86 added sections 1876(i)(6) and 1903(m)(5) of the Act. These provisions authorize a civil monetary penalty not greater than $10,000 for each instance of failure by an organization with a Medicare risk contract, or an organization that contracts under Medicaid, to provide required medically necessary items or services to Medicare or Medicaid enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee.

2. The Medicare and Medicaid Patient and Program Protection Act of 1987

Section 7 of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), added section 1902(p) of the Act which grants States the authority to exclude individuals or entities from participation in their Medicaid programs for any of the reasons that constitute a basis for exclusion from Medicare under section 1128, 1128A, or 1866(b)(2) of the Act. In addition, section 7 of MMPPPA established a new condition that States must meet in order to receive Federal Medicaid matching funds, known as Federal financial participation (FFP), for payments to HMOs or entities furnishing services under a waiver approved under section 1915(b)(1) of the Act. The new authority conditioned FFP upon a State's providing that it will exclude from participation, as an HMO or an entity furnishing services under a section 1915(b)(1) waiver, any entity that could be excluded under section 1128(b)(8) of the Act (i.e. any individual or entity against whom criminal or civil penalties have been imposed. FFP is also conditioned upon a State excluding an entity that has, directly or indirectly, a substantial contractual relationship with

an individual or entity that is described in section 1128(b)(8)(B) of the Act.

3. The Omnibus Budget Reconciliation Act of 1987

Section 4014 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100–203, provides the Department with increased penalty amounts and greater statutory authority and flexibility to take action against HMOs or CMPs that commit certain abuses. This authority also may be exercised in addition to or in lieu of initiating contract termination proceedings. Section 4014 of OBRA 87 amends section 1876(i)(6) of the Act by authorizing the Secretary to impose civil monetary penalties, suspend enrollment, and suspend payments for newly enrolled individuals in the case of an organization with a Medicare contract (both risk and cost contract) that he determines has (1) failed substantially to provide required medically necessary items and services to Medicare enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicare enrollees in excess of permitted premium amounts; (3) acted to expel or refused to re-enroll an individual in violation of section 1876; (4) engaged in any practice which can reasonably be expected to deny or discourage enrollment (except as permitted under section 1876) by Medicare enrollees whose medical condition or history indicates a need for substantial future medical services; (5) misrepresented or falsified information provided under section 1876 to the Secretary, an individual, or any other entity; or (6) fails to comply with the requirements of section 1876(g)(6)(A) regarding prompt payment of claims. Under OBRA 87, the maximum allowable civil monetary penalty that can be imposed for each determination of a violation was increased to $25,000, or $100,000 in the case of a HMO or CMP determined to have committed acts in (4) above or for misrepresenting or falsifying information furnished to the Secretary under section 1876.

4. The Medicare Catastrophic Coverage Act of 1988

The Medicare Catastrophic Coverage Act of 1988 (MCCA), Public Law 100–360, amended sections 1876 and 1903(m) of the Act by adding new civil monetary penalty authority for violations occurring within the Medicare program, and by applying the OBRA 87 HMO and CMP intermediate sanction and civil monetary penalty authority to the Medicaid program.

Section 224 of MCCA amended section 1876(i)(6)(B)(i) of the Act. In addition to other civil monetary penalties, in cases where Medicare enrollees are charged more than the allowable premium, section 224 imposes a penalty which doubles the amount of excess premium charged by the HMO or CMP. The excess premium amount is deducted from the penalty and returned to the Medicare enrollee. Section 224 also imposes a $15,000 penalty for each individual not enrolled when it is determined that the HMO or CMP engaged in any practice which denied or discouraged enrollment (except as permitted under section 1876) by Medicare enrollees whose medical condition or history indicated a need for substantial future medical services.

Section 411(k)(12) of MCCA amended section 1903(m)(5) of the Act by providing the Secretary with authority to impose civil monetary penalties on contracting organizations, and to deny payments for new enrollees of contracting organizations, in cases where he determines that an organization has (1) failed substantially to provide required medically necessary items and services to Medicaid enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicaid enrollees in excess of premium amounts permitted under title XIX; (3) discriminated among individuals in violation of the provisions of section 1903(m)(2)(A)(v), including expelling or refusing to re-enroll an individual or engaging in any practice which could reasonably be expected to deny or discourage enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicates a need for substantial future medical services; or (4) misrepresented or falsified information provided under section 1903 to the Secretary, State, an individual, or any other entity.

Under the amendments to section 1903(m)(5) made by MCCA, the maximum allowable civil monetary penalty that can be imposed for each determination of a violation is increased to $25,000, or $100,000 in the case of a deterination that a contracting organization has (1) violated the provisions of section 1903(m)(2)(A)(v) by expelling or refusing to re-enroll an individual or by engaging in a practice which denied or discouraged enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services; or (2) misrepresented or falsified information furnished to the Secretary or State under section 1903(m).

Additionally, in cases where Medicaid enrollees are charged more than the allowable premium, section 411(k)(12) of MCCA amended section 1903(m)(5) to authorize imposition of an additional penalty which doubles the amount of excess premium charged by the contracting organization, with the excess premium amount deducted from the penalty and returned to the Medicaid enrollee. Imposition of an additional $15,000 penalty is authorized for each individual not enrolled when it is determined that the contracting organization has violated the provisions of section 1903(m)(2)(A)(v) by expelling or refusing to re-enroll an individual or by engaging in any practice which denied or discouraged enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services.

5. The Omnibus Budget Reconciliation Act of 1989

Public Law 101–239, the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), amended sections 1876 and 1902(p) of the Act by providing the Secretary with an additional civil monetary penalty and intermediate sanction authority for violations occurring within the Medicare program, and an additional intermediate sanction authority for violations involving the Medicaid program.

Section 6411(d)(3)(A) of OBRA 89 amended section 1876(i)(6)(A) of the Act by authorizing the Secretary to restrict enrollment in, suspend payment to, and impose a civil monetary penalty against an organization with a risk contract that (1) employs or contracts with any individual or entity excluded from Medicare participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity. The maximum allowable civil monetary penalty that may be imposed for each determination of a violation of this nature is $25,000.

Section 6411(d)(3)(B) of OBRA 89 amended section 902(p)(2) of the Act to condition FFP in payments to HMOs, or to entities furnishing services under a section 1915(b)(1) waiver, upon the State's barring the following entities from participation as HMOs or section

2925(b)(1) waiver participants: (1) Any organization that employs or contracts with any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) any organization that employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

II. Provisions of the Proposed Regulation

These proposed regulations would amend 42 CFR part 417, subpart C; part 431, subpart B; part 434, subparts C, D, E, and F; and part 1003 specifically by establishing intermediate sanctions and civil monetary penalties which may be imposed on contracting organizations that substantially fail to provide an enrollee with required medically necessary items and services, or that engage in certain marketing, enrollment, reporting claims payment, employment, or contracting abuses.

A. Intermediate Sanctions

1. Medicare

HCFA proposes to incorporate the Medicare intermediate sanction provisions of OBRA 86, OBRA 87, MCCA, and OBRA 89 into agency regulations largely without substantial modifications. These changes would be added to 42 CFR part 417, subpart C under a new § 417.495, "Sanctions against the organization." Under these proposed regulations, if HCFA determines that a violation subject to an intermediate sanction has occurred, HCFA may provide, in lieu of contract termination proceedings, written notice to the organization describing the nature of the violation and a proposed intermediate sanction. The intermediate sanction would either (1) require that the HMO or CMP suspend applications for enrollment from Medicare beneficiaries or (2) provide that payments to the HMO or CMP be suspended for individuals who apply for enrollment after a date specified by HCFA. HCFA would also forward any determination that a violation has occurred to the Office of the Inspector General (OIG), which may impose a civil monetary penalty in addition to, or in lieu of, any intermediate sanctions that may be imposed by HCFA.

In general, HCFA would base any intermediate sanction notice on the nature, scope, severity and duration of the violation as well as the threat to patient health and safety. The organization's prior contract performance would also be considered when a determination is made.

The organization would have 15 days after receiving the notice to provide evidence that no violation has occurred, or to submit other pertinent information. If timely submitted, this evidence or information would be reviewed by a HCFA official who did not participate in the initial decision. Upon reaching a decision after reconsideration, the organization would receive notice of such determination accompanied by a brief written decision setting forth the factual and legal basis for the sanction. The effective date of the sanction would be 15 days after the organization receives notice of HCFA's initial decision to impose a sanction, unless the organization timely seeks reconsideration of that decision. If the organization timely seeks reconsideration, the sanction would be effective on the date the organization receives notice of HCFA's final decision on review, unless HCFA determines that the organization's conduct poses a serious threat to an enrollee's health and safety, in which case the effective date would be the date of notice of the initial determination.

The intermediate sanction would remain in effect until HCFA was satisfied that the problem was corrected and was not likely to recur. The organization's written response and HCFA's final determination would be provided to the Office of Inspector General (OIG).

We have not in these proposed regulations provided for further administrative review of a decision to impose intermediate sanctions. We would be interested in receiving comments on the question of whether such further administrative review would be useful or advisable, and, if so, what form it should take.

2. Medicaid

Unlike the Medicare program, the Medicaid program is administered by State governments, pursuant to Federal statutory and regulatory requirements, and a Medicaid "State plan" approved by HCFA. State governments thus are responsible for contracting with HMOs and other prepaid health plans, as well as monitoring such contracts. In the case of Medicaid contracts, therefore, we believe that States are in the best position to monitor for the violations discussed above, to make determinations as to whether a violation has occurred, and to recommend intermediate sanctions based upon the nature of the violation. HCFA therefore is proposing to rely upon States to perform, in the first instance, the same monitoring and sanction functions in the Medicaid program that HCFA will perform in the Medicare program. Each State would be required to set forth, in its State plan, procedures for: (1) Monitoring for violations; (2) determining whether a violation has occurred; and (3) recommending intermediate sanctions in accordance with these regulations.

The proposed Medicaid regulations would be set forth in 42 CFR part 431 and subparts C, D, E, and F of 42 CFR part 434. Under proposed § 434.63(c), States would be responsible for monitoring for the violations described in section 1903(m)(5)(A) of the Act. Under a proposed new § 434.67, States would be responsible for (1) making determinations as to whether a section 1903(m)(5)(A) violation has been committed by an HMO, (2) making a recommendation to HCFA as to whether an intermediate sanction should be imposed, and (3) reviewing evidence or information submitted by HMOs that wish to contest the imposition of intermediate sanctions. Under § 434.67(b)(1), a State determination that a violation has occurred would be sent to HCFA for review, and would become "the Secretary's" determination, for purposes of section 1903(m)(5)(A), if HCFA declines to reverse or modify the State finding within 15 days. Under § 434.67(g), a violation determination that is adopted as HCFA's would be forwarded to OIG for consideration of civil money penalties pursuant to the same process that applies to Medicare contracts.

Under § 434.67(b)(2), a State recommendation to HCFA that an intermediate sanction be imposed similarly would become "the Secretary's" determination, for purposes of section 1903(m)(5)(B)(ii), unless HCFA informs the States within 15 days that it disagrees with the recommendation. If a State's recommendation that a sanction be imposed becomes "the Secretary's" determination, the State would be required under § 434.67(c) to notify the HMO of this determination, and of its effect on payments to the HMO. In order to ensure that the intermediate sanction in section 1903(m)(5)(B)(ii) has its intended impact on the HMO found to have committed the violation, proposed §§ 434.22 and 434.42 would require that comprehensive risk contracts require that State payment for new enrollees be denied whenever Federal payment for such enrollees is denied pursuant to section 1903(m)(5)(B)(ii).

Under § 434.67(c), an HMO would have 15 days to provide the State with evidence that no violation has occurred,

or to submit other pertinent information. Under § 434.67(d), timely submitted evidence or other information would be reviewed by a State official who did not participate in the initial decision. Upon reaching a decision after reconsideration, the State would prepare a brief written decision setting forth the factual and legal basis for the decision. This decision would then be forwarded to HCFA, and constitute HCFA's determination if HCFA does not reverse or modify the decision within 15 days.

Under § 434.67(f), the effective date of the sanction would be, as appropriate, one of the following:

(1) In situations where the HMO does not timely appeal for a reconsideration, the date the HMO received notice of the Secretary's determination to impose sanctions; or

(2) When a timely appeal is made, the date the HMO received notification from the State of the reconsideration decision on review; or

(3) When HCFA, in consultation with the State agency, determines that the HMO's conduct poses a serious threat to an enrollee's health and safety, a date prior to an issuance of the decision under (1) or (2).

In all cases, it would be effective with respect to enrollees that apply for enrollment after the effective date of the sanction. The intermediate sanction would remain in effect until HCFA, in consultation with the State, was satisfied that HMO violation was corrected and was not likely to recur. The HMO's written submission and the final determination on review would also be forwarded by HCFA to OIG.

Under § 434.67(h), HCFA would retain concurrent authority to perform independently, at its discretion, the monitoring and sanction functions assigned to the States by these proposed rules.

Section 434.67(i) would require the State to document, in its State plan, a plan for monitoring for violations specified in § 434.67(a) and for implementing the provisions found in § 434.67 (b) through (g).

We have not in these proposed regulations provided for further administrative review by States or HCFA of decisions to impose intermediate sanctions under section 1903(m)(5)(B)(ii). We would be interested in receiving comments on the question of whether such further administrative review would be useful or advisable, and, if so, what form it should take.

Finally, proposed §§ 431.55 and 434.80 would implement the provision in section 1902(p) which establishes a new condition for FFP in payments to HMOs or entities furnishing services under a waiver approved under section 1915(b)(1) of the Act. These proposed regulations would implement the provision in section 902(p)(2) conditioning such FFP on the State's providing that it will "exclude from participation," as an HMO or an entity furnishing services under a section 1915(b)(1) waiver, any entity that (a) could be excluded under section 1128(b)(8) of the Act; (b) has, directly or indirectly, a substantial contractual relationship with an individual or entity that is described in section 1128(b)(8)(B) of the Act; or (c) employs or contracts with any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services, or any organization that employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity. "Substantial contractual relationship" is defined, at § 431.55(i)(2), to mean any contractual relationship that provides for administrative, management, or provision of medical services or the establishment of policies or operational support related to these activities. Section 431.55(i)(3) would require the State to submit, as part of its 1915(b)(1) waiver request, assurances that the entities described above are excluded from participation in the waiver program.

B. Civil Monetary Penalties

Under these proposed regulations, after HCFA determines that a contracting organization has committed a violation under § 1876(i)(6)(A) or 1903(m)(5)(A), information pertaining to the violation will be provided to the OIG. The OIG may then impose a civil monetary penalty in addition to or in lieu of other remedies available under law. The OIG may impose a civil monetary penalty of up to $25,000 for each determination that a contracting organization (1) failed substantially to provide required medically necessary items and services to Medicare or Medicaid enrollees, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee; (2) imposed premiums on Medicare or Medicaid enrollees in excess of permitted premium amounts; (3) acted to expel or refuse to re-enroll a Medicare beneficiary in violation of section 1876 of the Act; (4) misrepresented or falsified information provided under sections 1876 or 1903(m) of the Act to an individual, or any other entity; or (5) failed to comply with the requirements of section 1876(g)(6)(A) of the Act regarding prompt payment of claims. A civil monetary penalty of up to $25,000 may also be imposed for each determination that a contracting organization with a Medicare risk contract (1) employs or contracts with any individual or entity excluded from participation in Medicare under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or (2) employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

A civil monetary penalty of up to $100,000 may be imposed for each determination that a contracting organization has (1) misrepresented or falsified information provided to the Secretary under section 1876 of the Act, or provided to the Secretary or State under section 1903(m) of the Act; (2) engaged in any practice which could reasonably be expected to result in denying or discouraging enrollment (except as permitted under section 1876) by Medicare beneficiaries whose medical condition or history indicates a need for substantial future medical services; or (3) violated the provisions of section 1903(m)(2)(A)(v) of the Act, including expelling or refusing to re-enroll an individual or engaging in any practice which could reasonably be expected to result in denying or discouraging enrollment (except as permitted under section 1903(m)) by Medicaid recipients whose medical condition or history indicated a need for substantial future medical services.

In cases where Medicare or Medicaid enrollees are charged more than the allowable premium, an additional penalty which doubles the amount of excess premium charged by the contracting organization will be imposed. The excess premium amount will be deducted from the penalty and returned to the enrollee. A $15,000 penalty will be imposed for each individual not enrolled when it is determined that a contracting organization has committed a violation described in section 1876(i)(6)(A)(iv) or section 1903(m)(5)(A)(iii) (i.e. expelling or refusing to re-enroll a Medicaid recipient or engaging in any practice which effectively denied or discouraged enrollment (except as permitted under sections 1876 or 1903) by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicated a need for substantial future medical services).

Contracting organizations assessed civil monetary penalties under this regulation would be permitted to request a hearing before an Administrative Law Judge in accordance with the procedures currently set forth in 42 CFR part 1003.

C. Factors To Be Considered in Levying Civil Monetary Penalties

The following factors would be set forth in 42 CFR 1003.106 to consider in determining civil monetary penalty amounts:

- The nature of the appropriate item or service not provided and the circumstances under which it was not provided. It would be considered a mitigating circumstance if, where more than one violation exists, the appropriate items or services not provided were (1) few in number, or (2) of the same type and occurred within a short period of time. It would be considered an aggravating circumstance if such items or services were of several types and occurred over a lengthy period of time, or if there were many such items or services (or the nature and circumstances indicate a pattern of such items or services not being provided).
- The degree of culpability of the contracting organization. It would be considered a mitigating circumstance if the violation was the result of an unintentional, unrecognized error, and corrective action was taken promptly after discovery of the error.
- The seriousness of the adverse effect that resulted or could have resulted from any failure to provide required care. It would be considered an aggravating circumstance if the failure to provide required care was attributable to an individual or entity that the contracting organization is expressly prohibited by law from contracting or employing.
- The harm to the enrollee which resulted or could have resulted from the provision of care by an individual or entity that the contracting organization is expressly prohibited by law from contracting or employing. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in the prohibited practice of contracting or employing, either directly or indirectly, individuals or entities excluded from the Medicare program under sections 1128 or 1128A of the Act.
- The harm to the enrollee which resulted or could have resulted from expulsion or refusal to re-enroll by the contracting organization. It would be considered an aggravating factor if the contracting organization knowingly or routinely engages in any discriminatory or other prohibited practice which has the effect of denying or discouraging enrollment by individuals whose medical condition or history indicates a need for substantial future medical services.
- The nature and seriousness of the misrepresentative or fallacious information furnished by the contracting organization, under sections 1876 or 1903(m) of the Act, to the Secretary, State, enrollee, or any other entity.
- The history of prior offenses by the contracting organization or the principals of the contracting organization. It would be considered an aggravating circumstance if at any time prior to determination of the current violation or violations, the contracting organization or any of its principals was convicted on criminal charges or held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services. The lack of prior liability for criminal, civil, or administrative sanctions by the contracting organization, or the principals of the contracting organization, would not necessarily be considered a mitigating circumstance in determining civil monetary penalty amounts.
- Other such matters as justice may require.

Comments are specifically welcomed on the application of these criteria, and on the inclusion of other specific aggravating and mitigating factors to be considered in levying civil monetary penalties under this provision.

D. Alternatives Considered

The proposed regulations provide for a single determination made by HCFA to be the basis for both the intermediate sanctions and civil monetary penalties. However, the Department considered requiring separate determinations for the intermediate sanctions applied by HCFA and the civil monetary penalties imposed by OIG. The single determination approach was adopted because the Department believes it to be consistent with statutory intent that there be one determination by the Secretary which can result in various remedies. In addition, dividing the determination authority between different components within the Department would be inefficient and could result in less consistency and coherence. HCFA is delegated authority for actions under sections 1876 and 1903(m) of the Act and, with the exception of States in the case of Medicaid, is most directly involved in the operational activities of contracting organizations. To assure that the intermediate sanction and civil monetary penalty processes are coordinated, the proposed regulation includes a stipulation that all determinations made by HCFA will be routinely communicated to the OIG.

Consideration was also given to having HCFA, as opposed to States, monitor for violations by Medicaid contracting HMOs. However, State Medicaid Agencies already have the authority, personnel, and procedures established to monitor provisions of such contracts. Therefore, it is believed that State Agencies are the more appropriate entity to monitor for the specified violations and to implement certain activities related to intermediate sanctions.

III. Regulatory Impact Statement

A. Executive Order 12291

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed rule that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule would implement sections 9312(c)(2), 9312(f) and 9434(b) of Public Law 99–509; section 4014 of Public Law 100–203; sections 224 and 411(k)(12) of Public Law 100–360; and section 6411(d)(3) of Public Law 101–239. This proposed rule would broaden the Secretary's authority to impose intermediate sanctions and civil monetary penalties on HMOs, CMPs or other contracting organizations that (1) fail substantially to provide required medically necessary items and services to Medicare beneficiaries or Medicaid enrollees or (2) practice certain marketing, enrollment, reporting or claims payment abuses.

These provisions are the result of statutory changes and serve to clarify Departmental policy with respect to the imposition of intermediate sanctions and civil monetary penalties. We believe the majority of providers and practitioners do not engage in the prohibited activities and practices discussed in these proposed regulations.

In addition, we believe these proposed regulations would have a deterrent effect upon providers and practitioners. Therefore, we expect that the aggregate economic impact would be minimal, affecting only those engaged in the prohibited behavior in violation of statutory intent.

This proposed rule does not meet the $100 million criterion, nor do we believe that it meets the other E.O. 12291 criteria. Therefore, this proposed rule is not a major rule under E.O. 12291, and an initial regulatory impact analysis is not required.

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all HMOs, CMPs and other contracting organizations to be small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We do not have data to assist us in estimating the number of contracting organizations that would be affected by these proposed regulations or the magnitude of any penalties that would be imposed. As discussed under E.O. 12291, we believe any impact would be minimal because the majority of providers and practitioners engaged in prohibited activities would be few. In addition, this rule largely conforms our regulations to the Act.

Since we have determined, and the Secretary has certified, that this proposed rule would not result in a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals, we are not preparing analyses for either the RFA or small rural hospitals.

IV. Paperwork Reduction Act

This proposed rule contains no information collection requirements; therefore, it does not qualify under the provisions of the Paperwork Reduction Act of 1980.

List of Subjects

42 CFR Part 417

Administrative practice and procedure; Health Maintenance Organizations (HMO); Medicare; Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—Health; Health facilities; Medicaid; Privacy; Reporting and Recordkeeping requirements.

42 CFR Part 434

Grant programs—Health; Health Maintenance Organizations (HMO); Medicaid; Reporting and recordkeeping requirements.

42 CFR Part 1003

Administrative practice and procedure; Fraud; Grant programs—Health; Health facilities; Health Professions; Maternal and Child Health; Medicaid; Medicare; Penalties.

A. 42 CFR part 417 would be amended as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 would be revised to read as follows:

Authority: 31 U.S.C. 9701, 42 U.S.C. 300e through 300e-17, 1302, 13951(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, 1395mm, and 1395m note.

2. The table of contents for part 417, subpart C, would be amended by adding new § 417.495 to read as follows:

* * * * *

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

* * * * *

417.495 Sanctions against the organization.

* * * * *

Subpart C—Health Maintenance Organizations and Competitive Medical Plans

3. In subpart C, a new § 417.495 would be added to read as follows:

§ 417.495 Sanctions against the organization.

(a) *Basis for application of sanctions.* HCFA may apply intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination, if HCFA determines that an organization with a contract under this part—

(1) Fails substantially to provide medically necessary items and services that are required to be provided to an individual covered under the contract, and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(2) Imposes premiums on individuals enrolled under this part in excess of premiums permitted;

(3) Acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) with the organization by eligible individuals whose medical condition or history indicates a need for substantial future medical services;

(5) Misrepresents or falsifies information that is furnished—

(i) To HCFA under this part;

(ii) To an individual or to any other entity under this part;

(6) Fails to comply with the requirements of section 1876(g)(6)(A) of the Act relating to the prompt payment of claims;

(7) Fails to meet the requirement in section 1876(f)(1) of the Act that not more than 50 percent of the organization's enrollment may be Medicare beneficiaries and Medicaid recipients; or

(8) Has a Medicare risk contract and—

(i) Employs or contracts with individuals or entities excluded from participation in Medicare under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

(b) *Notice of intermediate sanction.* Prior to applying the sanctions specified in paragraph (d) of this section, HCFA will send a written notice to the organization stating the nature and basis of the proposed sanction. A copy of the notice (other than a notice for the violation described in paragraph (a)(7) of this section) will be forwarded to the OIG at the same time that it is sent to the organization. HCFA will allow the organization 15 days after the date it receives the notice to provide evidence that the organization has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable.

(c) *Informal reconsideration.* If the organization submits a timely response to HCFA's notice of intermediate sanction, HCFA will conduct an informal reconsideration that includes:

(1) Review of the evidence by a HCFA official who did not participate in the initial decision to impose a sanction; and

(2) If the decision to impose a sanction is affirmed on review, forwarding to the organization a concise written decision setting forth the factual and legal basis for the decision.

(d) *Intermediate sanctions.* If HCFA determines that an organization has committed a violation described in paragraph (a) of this section and this determination is affirmed on review in the event the organization timely contests the determination under paragraph (b) of this section, HCFA may—

(1) Require the organization to suspend new applications for enrollment from Medicare beneficiaries after the effective date in paragraph (e)(1) of this section; or

(2) Suspend payments to the organization for any individuals who apply for enrollment after the effective date in paragraph (e)(1) of this section.

(e) *Effective date and duration of intermediate sanctions.* (1) Intermediate sanctions will be made effective 15 days after the date that the organization is notified of the decision to impose the sanctions, unless the organization timely seeks reconsideration under paragraph (c) of this section, in which case the intermediate sanction generally will be effective on the date the organization is notified of HCFA's decision under paragraph (c)(2) of this section.

(2) If HCFA determines that the organization's conduct poses a serious threat to an enrollees' health and safety, the intermediate sanction may be made effective on a date prior to issuance of HCFA's decision under paragraph (c)(2) of this section.

(3) The sanction will remain in effect until HCFA notifies the organization that HCFA is satisfied that the basis for applying the sanction has been corrected and is not likely to recur.

(f) *Termination by HCFA.* As an alternative to the sanctions described in paragraph (d) of this section, HCFA may decline to renew an organization's contract in accordance with § 417.492(b), or terminate its contract in accordance with § 417.494(b).

(g) *Civil monetary penalties.* If HCFA determines that an organization has committed an act or failed to comply with a requirement described in paragraph (a) of this section (with the exception of the violation described in paragraph (a)(7) of this section), HCFA will convey such determination to the Office of Inspector General. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil monetary penalties on the organization in addition to or in lieu of the intermediate sanctions imposed by HCFA.

B. 42 CFR part 431 would be amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1396(a)(4), 1396a(p)(2), and 1396b.

2. In subpart B, § 431.55 would be amended by revising paragraph (a) and adding new paragraph (h) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

(A) *Statutory basis.* Section 1915(b) of the Act authorizes the Secretary to waive the requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost-effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (e), (f), and (h) of the Act prescribe how such waivers are to be approved, continued, monitored, and terminated. Sections 1916 (a)(3) and (b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 2925(b)(1) waiver on the State's provision for excluding certain entities from participation.

* * * * *

(h)(1) FFP in payments to an entity furnishing services under a waiver approved under section 1915(b)(1) is available only if the agency provides that it will exclude from participation as such any entity that—

(i) Could be excluded under section 1128(b)(8) of the Act;

(ii) Has a substantial contractual relationship, either directly or indirectly as defined in § 431.55(h)(2), with an individual described in section 1128(b)(8)(B) of the Act; or

(iii) Employs or contracts with—

(A) Any individual or entity excluded from Medicaid participation under sections 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(B) Any entity, directly or indirectly, for the provision through an excluded individual or entity of such services described in paragraph (h)(1)(iii)(A) of this section.

(2) A *substantial contractual relationship* is any contractual relationship which provides for one or more of the following services:

(i) The administration, management, or provision of medical services;

(ii) The establishment of policies pertaining to the administration, management or provision of medical services; or

(iii) The provision of operational support for the administration, management, or provision of medical services.

(3) The agency must submit, as part of its section 1915(b)(1) waiver request, assurances that the entities described in paragraph (h)(1) of this section are excluded from participation under an approved waiver.

C. 42 CFR part 434 would be amended as set forth below:

PART 434—CONTRACTS

1. The authority citation for part 434 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 396(a)(4), 1396a(p)(2), and 1396b.

2. The table of contents for part 434 would be amended by adding new § 434.22 to subpart C, 434.42 to subpart D, 434.67 to subpart E, and 434.80 to subpart F to read as follows:

* * * * *

Subpart C—Contracts With HMOs and PHPs: Contract Requirements

* * * * *

434.22 Application of intermediate sanctions to comprehensive risk contracts.

* * * * *

Subpart D—Contracts with Health Insuring Organizations

* * * * *

434.42 Application of intermediate sanctions to comprehensive risk contracts.

* * * * *

Subpart E—Contracts With HMOs and PHPs: Medicaid agency responsibilities

* * * * *

434.67 Sanctions against HMOs with comprehensive risk contracts.

* * * * *

Subpart F—Federal Financial Participation

* * * * *

434.80 Conditions for FFP in contracts with HMOs.

* * * * *

Subpart C—Contracts with MOs and PHPs: Contract requirements

3. In Subpart C, a new § 434.22 would be added as follows:

§ 434.22 Application of intermediate sanctions to comprehensive risk contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for such enrollees is denied by HCFA pursuant to § 434.67(e).

Subpart D—Contracts With Health Insuring Organizations

4. In subpart D, a new § 434.42 would be added as follows:

§ 434.42 Application of intermediate sanctions to comprehensive risk contracts.

A risk comprehensive contract must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for such enrollees is denied by HCFA pursuant to § 434.67(e).

Subpart E—Contracts With HMOs and PHPs: Medicaid Agency Responsibilities

5. Subpart E, § 434.63 would be revised to read as follows:

§ 434.63 Monitoring procedures.

The agency must have procedures to—

(a) Monitor enrollment and termination practices;

(b) Insure proper implementation of the contractor's grievance procedures; and

(c) Monitor for violations of the requirements specified in § 434.67 and the conditions necessary for FFP in contracts with HMOs, specified in § 434.80.

Subpart E—Contracts With HMOs and PHPs: Medicaid Agency Responsibilities

6. In Subpart E, new § 434.67 would be added to read as follows:

§ 434.67 Sanctions against HMOs with comprehensive risk contracts.

(a) *Basis for application of sanctions.* The agency may recommend that the intermediate sanction specified in paragraph (e) of this section be imposed if the agency determines that an HMO with a comprehensive risk contract—

(1) Fails substantially to provide medically necessary items and services that are required under law or under the contract to be provided to an individual covered under the contract, and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(2) Imposes premiums on individuals covered under the contract in excess of premiums permitted;

(3) Engages in any practice that discriminates among individuals on the basis of their health status or requirements for health care services, including expulsion or refusal to re-enroll an individual, or any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1903(m) of the Act) by eligible individuals whose medical condition or history indicates a need for substantial future medical services; or

(4) Misrepresents or falsifies information that is furnished—

(i) To HCFA or the State agency under section 1903(m); or

(ii) To an individual or to any other entity under section 1903(m).

(b) *Effect of an agency determination.* (1) When the agency determines that an HMO with a comprehensive risk contract has committed one of the violations identified in paragraph (a) of this section, the agency must forward this determination to HCFA. This determination becomes HCFA's determination for purposes of section 1903(m)(5)(A) of the Act, if HCFA does not reverse or modify the determination within 15 days.

(2) When the agency decides to recommend imposition of the intermediate sanction specified in paragraph (e) of this section, this recommendation becomes HCFA's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, if HCFA does not reject this recommendation within 15 days.

(c) *Notice of intermediate sanction.* If a determination to impose intermediate sanctions becomes HCFA's determination pursuant to paragraph (b)(2) of this section, the agency must send a written notice to the HMO stating the nature and basis of the proposed sanction. A copy of the notice will be forwarded to the OIG at the same time that it is sent to the organization. The agency will allow the HMO 15 days after the date it receives the notice to provide evidence that the HMO has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable.

(d) *Informal reconsideration.* (1) If the HMO submits a timely response to the agency's notice of intermediate sanction, the agency will conduct an informal reconsideration that includes—

(i) Review of the evidence by an agency official who did not participate in the initial recommendation to impose a sanction; and

(ii) A concise written decision setting forth the factual and legal basis for the decision.

(2) The agency decision under paragraph (d)(1)(ii) of this section will be forwarded to HCFA and will become HCFA's decision if HCFA does not reverse or modify the decision within 15 days. The agency will send the HMO a copy of HCFA's decision under this subparagraph.

(e) *Intermediate sanction.* If a HCFA determination that a HMO has committed a violation described in paragraph (a) of this section is affirmed on review under paragraph (d) of this section, or is not timely contested by the HMO under paragraph (c) of this section, then HCFA, based upon the recommendation of the agency, may deny payment for new enrollees of the HMO pursuant to section 1903(m)(5)(B)(ii) of the Act. Under §§ 434.22 and 434.42, this denial of payment by HCFA for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. A "new enrollee" is defined as an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.

(f) *Effective date and duration of intermediate sanction.* (1) Unless an HMO timely seeks a reconsideration pursuant to paragraph (d) of this section or HCFA determines the violation poses a serious threat to enrollees health or safety, intermediate sanctions will be made effective 15 days after the date that the HMO is notified of the HFCA decision to impose the sanction pursuant to paragraph (c) of this section. If the HMO seeks reconsiderations under paragraph (d) of this section, the intermediate sanction generally will be effective on the date the organization is notified of HCFA's decision under paragraph (d)(1)(ii) of this section.

(2) If HCFA, in consultation with the agency determines that the HMO's conduct poses a serious threat to an enrollees' health and safety, the intermediate sanction may be made effective on a date prior to issuance of the decision under paragraph (d)(1)(ii) of this section.

(3) The sanction will remain in effect until HCFA, in consultation with the agency, is satisfied that the basis for applying the sanction has been corrected and is not likely to recur.

(g) *Civil monetary penalties.* If a determination that an organization has committed a violation under paragraph (a) of this section becomes HCFA's determination under paragraph (b)(1) of this section, HCFA will convey such determination to the Office of Inspector General. In accordance with the provisions of 42 CFR Part 1003, the OIG may impose civil monetary penalties on

the organization in addition to or in lieu of the intermediate sanctions imposed under this section.

(h) HCFA retains the right to independently perform the functions assigned to the agency in paragraphs (a) through (f) of this section.

(i) *State Plan Requirements.* The State Plan must include a plan to monitor for violations specified in paragraph (a) of this section and for implementing the provisions of this section.

Subpart F—Federal Financial Participation

7. In subpart F, a new § 434.60 would be added to read as follows:

§ 434.60 Condition for FFP in contracts with HMOs.

FFP in payments to an HMO is available only if the agency provides that it will exclude from participation as such an entity any entity that—

(a) Could be excluded under section 1128(b)(8) of the Act;

(b) Has a substantial contractual relationship, either directly or indirectly as defined in § 431.55(h)(2), with an individual described in section 1128(b)(8)(B) of the Act; or

(c) Employs or contracts with—

(1) Any individual or entity excluded from Medicaid participation under section 1128 or 1128A of the Act for the provision of health care, utilization review, medical social work, or administrative services; or

(2) Any entity, directly or indirectly, for the provision through an excluded individual or entity of such services described in paragraph (c)(1) of this section.

PART 1003—CIVIL MONEY PENALTIES AND ASSESSMENTS

D. 42 CFR part 1003 would be amended as set forth below:

1. The authority citation for part 1003 would be revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 1137(b)(2).

2. Section 1003.100 would be amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1842(j), 1842(k), 1876(i)(6), 1882(d), and 1903(m)(5) of the Social Security Act, and sections 421(c) and 427(b)(2) of Public Law 99–660 (42 U.S.C. 1320a–7(c), 1320a–7a, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2)).

(b) *Purpose.* This part—

(1) Establishes procedures for imposing:

(i) Civil money penalties and assessments against persons who have submitted certain prohibited claims under the Medicare, Medicaid, or the Maternal and Child Health Services Block Grant programs;

(ii) Civil money penalties against persons who fail to report information concerning medical malpractice payments or who improperly disclose, use, or permit access to information reported under Part B of Title IV of Public Law 99–660, and regulations specified in 45 CFR Part 60; and

(iii) Civil money penalties against contracting organizations that substantially fail to provide an enrollee with required medically necessary items and services, or that engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses;

* * * * *

3. Section 1003.101 would be amended by adding, in alphabetical order, definitions for the terms "adverse effect," "contracting organization," and "enrollee" to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

* * * * *

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient, or has placed the patient unnecessarily in a high-risk situation.

* * * * *

Contracting organization means a public or private entity, inclusive of a health maintenance organization (HMO), competitive medical plan (CMP), or health insuring organization (HIO) which meets the requirements of section 1876(b) or is subject to the requirements in section 1903(m)(2)(A) of the Social Security Act, and which has contracted with the Department or a State to provide medical items and services to Medicare beneficiaries or Medicaid recipients.

Enrollee means an individual who is eligible for Medicare or Medicaid, and who enters into an agreement to receive medical items and services from a contracting organization that contracts with the Department under titles XVIII or XIX of the Social Security Act.

* * * * *

4. Section 1003.102 would be amended by revising paragraph (b) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

* * * * *

(b) The OIG may impose a penalty against:

(1) Any person whom it determines in accordance with this part:

(i) Has presented or caused to be presented a request for payment in violation of the terms of:

(A) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(B) An agreement with a State agency not to charge a person for an item or service in excess of the amount permitted to be charged; or

(C) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(ii) Is a non-participating physician under section 1842(j) of the Act and has knowingly and willfully billed individuals enrolled under part B of title XVIII of the Act, during the statutory period of the freeze, for actual charges in excess of such physicians, actual charges for the calendar quarter beginning on April 1, 1984.

(iii) Is a physician who has knowingly and willfully—

(A) Billed for services as an assistant at surgery during a routine cataract operation, or

(B) Included in his or her bill the services of an assistant at surgery during a routine cataract operation; and has not received prior approval from the appropriate Peer Review Organization or Medicare carrier for such services based on the existence of a complicating medical condition.

(2) Any contracting organization that HCFA determines has committed an act or failed to comply with the requirements set forth in §§ 417.495(a) and 434.70(c)(1) of this title.

5. Section 1003.103 would be amended by adding a new paragraph (c) to read as follows:

§ 1003.103 Amount of penalty.

* * * * *

(c)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization has:

(i) Failed substantially to provide an enrollee with required medically necessary items and services, if the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Imposed premiums on enrollees in excess of amounts permitted under section 1876 or title XIX of the Act;

(iii) Acted to expel or to refuse to re-enroll a Medicare beneficiary in violation of the provisions of section 1876 of the Act, and for reasons other than the beneficiary's health status or requirements for health care services;

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or 1903(m) of the Act; or

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization with a contract under section 1876 of the Act:

(i) Employs or contracts with individuals or entitles excluded from participation in Medicare, under sections 1128 or 1128A of the Act, for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of such services (directly or indirectly) through an excluded individual or entity.

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has:

(i) Misrepresented or falsified information furnished to the Secretary under section 1876 of the Act, or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to re-enroll a Medicare beneficiary or Medicaid recipient because of the individual's health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or 1903(m) of the Act) with the contracting organization by enrollees whose medical condition or history indicates a need for substantial future medical services.

(4) In cases where enrollees are charged more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.

(5) The OIG will impose an additional $15,000 penalty for each individual not enrolled when it is determined that a contracting organization has committed a violation described in paragraph (c)(3)(ii) of this section.

(6) For purposes of paragraph (c) of this section, a violation is defined as each incident where a person has committed an act or failed to comply with a requirement set forth in § 417.495(a) or § 434.67(a), as determined by HCFA.

6. Section 1003.106 would be amended by revising paragraph (a)(1), redesignating paragraph (a)(2) as paragraph (a)(3), and adding new paragraph (a)(2) to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a)(1) In determining the appropriate amount of any penalty or assessment under § 1003.103(a), (b) and (c)(1)–(3), the OIG will consider:

(i) The nature of the claim or request for payment and the circumstances under which it was presented;

(ii) The degree of culpability of the person or contracting organization submitting the claim or request for payment;

(iii) The history of prior offenses of the person or contracting organization submitting the claim or request for payment;

(iv) The financial condition of the person or contracting organization presenting the claim or request for payment; and

(v) Such other matters as justice may require.

(2) In determining the appropriate amount of any penalty under § 1003.103(b)(4), the OIG will consider:

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under sections 1876(i)(6) or 1903(p)(2) of the Act, from contracting or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to re-enroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee, or other entity under sections 1876 or 1903(m) of the Act;

(vii) The history of prior offenses by the contracting organization, or principals of the contracting organization, including whether at any time prior to determination of the current violation or violations the contracting organization or any of its principals was convicted of a criminal charge, or was held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(viii) Such other matters as justice may require.

* * * * *

Dated: October 26, 1990.

Bryan Mitchell,

Acting Inspector General, Department of Health and Human Services.

Dated: October 4, 1990.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: April 3, 1991.

Louis W. Sullivan,

Secretary, Department of Health and Human Services.

[FR Doc. 91–16524 Filed 7–19–91; 8:45 am]

BILLING CODE 4110–60–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 91-211, RM-7548]

Radio Broadcasting Services; Tallulah, LA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Sharing, Inc., licensee of Station KBYO(FM), Channel 285A, Tallulah, Louisiana, seeking substitution of Channel 283C3 for Channel 285A and modification of its authorization accordingly. Channel 283C3 can be allotted to Tallulah in compliance with the Commission's minimum distance separation requirements at Station KBYO(FM)'s present transmitter site. The coordinates for Channel 283C3 at Tallulah are North Latitude 32–24–10 and West Longitude 91–04–00. In accordance with § 1.420(g) of the Commission's Rules, we will not accept competing expressions of interest in use of Channel 283C3 at Tallulah or require Sharing, Inc., to demonstrate the availability of an additional equivalent class channel.

DATES: Comments must be filed on or before September 6, 1991, and reply

comments on or before September 23, 1991.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Frank R. Jazzo, Esq., Robert D. Primosch, Esq., Fletcher, Heald & Hildreth, 1225 Connecticut Avenue, NW., Washington, DC 20036 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau, (202) 632-6302.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 91-211, adopted June 25, 1991, and released July 16, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center (202) 452-1422, 1714 21st Street NW., Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Andrew J. Rhodes,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 91-17281 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 91-212, RM-7727]

Radio Broadcasting Services; Kurten, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Kurten Broadcasting Company seeking the allotment of Channel 245A to Kurten, Texas, as the community's first local FM service. The petitioner is requested to submit additional information regarding Kurten's status as a community for allotment purposes. Channel 245A can be allotted to Kurten in compliance with the Commission's minimum distance separation requirements with a site restriction of 10.3 kilometers (6.4 miles) west to avoid a short-spacing to a construction permit for Channel 246C1, Cleveland, Texas, as well as to accommodate petitioner's desired site. The coordinates for Channel 245A are North Latitude 30-47-06 and West Longitude 96-22-15.

DATES: Comments must be filed on or before September 6, 1991, and reply comments on or before September 23, 1991.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Mark Fields, Esq., Miller & Fields, Post Office Box 33003, Washington, DC 20033 (Counsel to petitioner).

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau (202) 632-6302.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 91-212, adopted June 26, 1991, and released July 16, 1991. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1714 21st Street, NW., Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Andrew J. Rhodes,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 91-17282 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 76

[MM Docket No. 90-4, FCC 91-184]

Carriage of Television Broadcast Signals by Cable Television Systems

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In the Further Notice of Proposed Rule Making (56 FR 406, January 4, 1991) in this proceeding, the Commission sought comment regarding the relationship between its effective competition standard, which determines whether or not a cable system may be subject to basic cable rate regulation, and the absence of mandatory signal carriage rules. The record to date is too limited to definitively establish whether or not such a link exists. Thus, the Commission adopts this Second Further Notice of Proposed Rule Making requesting further comment on whether the lack of signal carriage requirements for cable television systems undermines the effective competition standard. This action is part of a combined Report and Order and Second Further Notice of Proposed Rule Making. In the Report and Order, the Commission modified its rules regarding the regulation of basic cable service rates by local franchising authorities pursuant to the Cable Communications Policy Act of 1984.

DATES: Comments are due September 25, 1991, and reply comments are due by October 25, 1991.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Marcia Glauberman, Mass Media Bureau, Policy and Rules Division, (202) 632-3410.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Second Further Notice of Proposed Rule Making in MM Docket No. 90-4, adopted June 13, 1991, and released July 12, 1991. The complete text of this Second Further Notice of Proposed Rule Making is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC, and also

may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1114 21st Street, NW., Washington, DC.

Synopsis of Second Further Notice of Proposed Rule Making

1. Section 623 of the Cable Communications Policy Act of 1984 (Cable Act) permits, but does not require, franchising authorities to regulate basic cable service rates only in situations where the cable system is not subject to "effective competition," as defined by the Commission. This proceeding was initiated to review the rules regarding the regulation of basic cable rates in light of changed circumstances since the Commission adopted a three over-the-air broadcast signal standard for determining whether effective competition exists in 1985.

2. In the Further Notice of Proposed Rule Making (Further Notice) in this proceeding, the Commission proposed a revised definition of effective competition and new standards for regulation of rates in the absence of effective competition. The Commission also observed that cable systems are no longer subject to the signal carriage obligations that were in effect when the Cable Act was adopted. Thus, the Further Notice sought comment on the relationship, if any, between the rules governing effective competition and the absence of signal carriage regulations.

3. In the Report and Order adopted concurrent with this Second Further Notice of Proposed Rule Making (Second Further Notice), the Commission modified its rule that defines what constitutes "effective competition" cable service. The revised rule, in part, would deem a cable system subject to effective competition if at least six unduplicated over-the-air broadcast signals were available over the entire cable community. With respect to the signal carriage issue, however, the Commission found that the record to date is too limited to definitively establish whether or not a link exists between effective competition and mandatory signal carriage. Accordingly, the Commission adopts this Second Further Notice to solicit further comment on this matter.

4. In the Second Further Notice, the Commission notes that must carry rules were in effect when Congress adopted the Cable Act in 1984. Since that time the courts have twice invalidated the Commission's must carry rules. *Quincy Cable TV, Inc.* v. *FCC*, 768 F.2d 1434 (DC Cir. 1985), *cert. denied*, 106 S.Ct. 2889 (1986); *Century Communications Corp.* v. *FCC*, 835 F.2d 292 (D.C. Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988). Notwithstanding this fact, there remains a continuing interest in the must carry issue.

5. The Commission observes that broadcasters believe that the effectiveness of a revised standard depends on whether the six over-the-air signals deemed to be effective competition to basic cable service are, in fact, carried on the system. The Commission also notes the continuing Congressional concern over the must carry issue. In addition, the Commission has long been concerned with the competitive imbalance between cable and broadcasting that has resulted in part from the elimination of must carry rules.

6. If noncarriage of local broadcast signals affects the ability of local stations to present programming that serves local needs and interests, the system of widely-available over-the-air broadcasting that Congress encouraged in the Communications Act could be undermined. This prospect is enhanced to the extent that cable subscribers lose their ability to access local stations not carried on cable. If these assertions are correct, and if broadcast stations are seriously debilitated as a result, the ability of six broadcast stations to offer effective competition to basic cable service may be questioned.

7. In the Second Further Notice, the Commission requests comment on whether it would be sound public policy for the Commission to further amend its effective competition rules so that a cable system will be considered subject to effective competition only where the six stations in question are carried by the cable system. Commenters are asked to provide specific information on the extent to which the lack of must carry rules has undermined effective competition. They are also asked to consider whether there are legal justifications, such as section 307(b) of the Communications Act, that may support reimposition of must carry rules, either in connection with the effective competition standard or separately.

8. The Commission recognizes that it can only impose must carry rules if they are found by the courts to be an incidental restriction on speech that furthers an important government interest and are no greater than is essential to the furtherance of that interest. This will require persuasive evidence of real harm to the broadcasting system's ability to serve the public interest and reasoned legal analysis supporting any action the Commission might take. Accordingly, commenters are requested to justify and correlate whatever policy arguments they advance with relevant judicial precedent.

Initial Regulatory Flexibility Act Analysis

9. Pursuant to the Regulatory Flexibility Act of 1980, the Commission finds:

I. *Reason for action.* The Cable Communications Policy Act of 1984 (Cable Act) requires the Commission to periodically review its rules regarding the regulation of basic cable service rates. This proceeding was initiated to reexamine the "effective competition" standard and standards for rate regulation adopted in 1985 in light of changed circumstances in the video marketplace. In the Further Notice of Proposed Rule Making, the Commission sought comment on the relationship, if any, between the rules governing effective competition and the elimination of mandatory signal carriage rules for cable systems since the enactment of the Cable Act. The revised rules adopted in the Report and Order, in part, would deem a cable system subject to effective competition if at least six unduplicated over-the-air broadcast signals were available over the entire cable community. However, the Commission found that the record regarding the must carry issue was too limited to establish whether a link exists between effective competition and the absence of signal carriage obligations. This Second Further Notice of Proposed Rule Making (Second Further Notice) requests additional comment on this matter.

II. *Objectives.* To consider whether or not the Commission's effective competition standard is undermined by the lack of signal carriage obligations. We wish to determine whether it would be sound public policy for the Commission for further amend the effective competition rules to require cable systems to carry the six over-the-air broadcast signals considered to provide effective competition to cable service. The Second Further Notice seeks information that will put the Commission "in a position to know" whether, in light of the realities of the contemporary video marketplace, must carry rules are needed and, if so, whether they may be constitutionally tailored to serve a substantial government interest and thereby address the concerns articulated by the court in its decisions invalidating previous must carry rules.

III. *Legal basis.* Action as proposed for this rule making is contained in sections 4(i), 303 and 543(b)(3) of the Communications Act of 1934 as

amended, 47 U.S.C. 4(1), 303 and 543(b)(3).

IV. *Reporting, recordkeeping and other compliance requirements.* None.

V. *Federal rules which overlap, duplicate or conflict with this rule.* None.

VI. *Description, potential impact and number of small entities affected.* Depending on the action taken as a result of this proceeding, cable systems may have the additional burden of meeting signal carriage requirements as part of the effective competition standard that determines whether they are exempt from rate regulation by their local franchising authorities. However, as cable systems may or may not be rate regulated, at the discretion of the franchising authority, we are unable to estimate the number of cable systems that would be affected if new must carry rules were adopted as a result of this proceeding.

VII. *Any significant alternatives minimizing impact on small entities and consistent with stated objective.* None.

10. The Secretary shall send a copy of this "Second Further Notice of Proposed Rule Making", including the initial regulatory flexibility analysis, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, Public Law No. 96-354, 94 Stat. 1164, 5 U.S.C. 601 et seq. (1981).

Ex Parte Consideration

11. This is a non-restricted notice and comment rulemaking proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rules. See generally 47 CFR 1.1202, 1.203, and 1.206(a).

Comment Information

12. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before September 25, 1991, and reply comments on or before October 25, 1991. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding.

13. Authority for this action is contained in sections 4(i), 303 and 543(b) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303 and 543(b).

List of Subjects in 47 CFR Part 76

Cable television.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-17106 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 662

[Docket No. 910770-1170]

Northern Anchovy Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of preliminary determination; request for comments.

SUMMARY: NOAA announces the estimated spawning biomass and preliminary determination of harvest quotas for the northern anchovy fishery in the exclusive economic zone (EEZ) south of Point Reyes, California, for the 1991-92 fishing season. The harvest quotas have been determined by application of the formulas in the Northern Anchovy Fishery Management Plan (FMP) and its implementing regulations. Those regulations require this announcement to be made on or about July 1 of each year for public comment. The U.S. optimum yield is set at 25,200 metric tons (mt), which includes a 20,3000 mt reduction quota and a 4,900 mt non-reduction quota, plus an unspecified amount for use as live bait. NOAA's final determination of the harvest quotas will be announced on or about August 1, 1991.

DATES: Comments must be received on or before August 15, 1991.

ADDRESSES: Comments should be addressed to E.C. Fullerton, Director, Southwest Region, NMFS, 300 South Ferry Street, Terminal Island, CA 90731.

FOR FURTHER INFORMATION CONTACT: James J. Morgan, Fisheries Management and Analysis Branch, Southwest Region, NMFS, Terminal Island, California, (213) 514-6667.

SUPPLEMENTARY INFORMATION: In consultation with the California Department of Fish and Game and the Southwest Fisheries Center, the Director of the Southwest Region, NMFS, (Regional Director) has made a preliminary determination that the spawning biomass of the central subpopulation of northern anchovy, *Engraulis mordax*, is estimated to be 329,000 mt. The biomass estimate is derived from the egg production method of measurement, which uses plankton samples to measure the abundance of newly spawned eggs. The cost of conducting such a survey every year is high; therefore, other sources of stock assessment data have been calibrated to the egg production method with the stock synthesis model.

The Regional Director has made the following preliminary determinations for the 1991-1992 fishing season by applying the formulas in the FMP and in § 662.20 of the implementing rules.

1. The total U.S. harvest quota, or optimum yield (OY), of northern anchovy is 25,200 mt, plus an unspecified amount for use as live bait.

2. The total U.S. harvest quota for reduction purposes is 20,300 mt.

a. Of the total reduction harvest quota, 2,030 mt is reserved for the reduction fishery in subarea A (north of Pt. Buchon).

b. The reduction quota for subarea B (south of Pt. Buchon) is 18,270 mt.

3. The U.S. harvest allocation for non-reduction fishing (i.e., fishing for anchovy for use as dead bait and human consumption) is 4,900 mt. Non-reduction fishing is not limited until the total catch in both the reduction and non-reduction fisheries reaches the total harvest quota of 25,200 mt.

4. There is no U.S. harvest limit for the live bait fishery.

5. The domestic annual processing capacity (DAP) is 3,208 mt. The FMP states that this amount is the maximum level of reduction plus non-reduction processing during the previous 3 years.

6. The amount allocated to joint venture processing (JVP) is zero because there is no history of, nor are there applications for, joint ventures.

7. Domestic annual harvest capacity (DAH) is 3,208 mt. DAH is the sum of DAP and JVP.

8. The total allowable level of foreign fishing (TALFF) is zero. The TALFF in the EEZ is based on the U.S. portion of the OY minus the DAH, minus that amount of the expected harvest in the Mexican fishery zone that is in excess of the amount allocated to Mexico by the FMP.

A summary of the information on which this preliminary determination is based has been provided to the Pacific Fishery Management Council (Council). Consultations with the Council will continue through early August. In addition, the Regional Director will consider until August 15, 1991, evidence received from domestic land-based processors that the preliminary DAP should be modified. A final determination of the harvest quotas will be announced on or about August 1, 1991.

Classification

This action is authorized by 50 CFR part 662 and complies with Executive Order 12291.

List of Subjects in 50 CFR Part 662

Fisheries.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 15, 1991.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 91-17273 Filed 7-16-91; 2:47 pm]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 56, No. 140
Monday, July 22, 1991

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meat Import Limitations; Third Quarterly Estimate

Public Law 88-482, enacted August 22, 1964, as amended by Public Law 96-177, Public Law 100-418, and Public Law 100-449 (hereinafter referred to as the "Act"), provides for limiting the quantity of fresh, chilled, or frozen meat of bovine, sheep except lamb, and goats; and processed meat of beef or veal (Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.20, 0201.20.40, 0201.20.60, 0201.30.20, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.20, 0202.20.40, 0202.20.60, 0202.30.20, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, and 0204.50.00), which may be imported, other than products of Canada, into the United States in any calendar year. Such limitations are to be imposed when the Secretary of Agriculture estimates that imports of articles, other than products of Canada, provided for in Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.40, 0201.20.60, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.40, 0202.20.60, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, 0204.43.40, and 0204.50.00 (hereinafter referred to as "meat articles"), in the absence of limitations under the Act during such calendar year, would equal or exceed 110 percent of the estimated aggregate quantity of meat articles prescribed for calendar year 1990 by subsection 2(c) as adjusted under subsection 2(d) of the Act.

As announced in the Notice published in the **Federal Register** on January 7, 1991 (56 FR 510), the estimated aggregate quantity of meat articles other than products of Canada prescribed by subsection 2(c) as adjusted by subsection 2(d) of the Act for calendar year 1991 is 1,198.6 million pounds.

In accordance with the requirements of the Act, I have determined that the third quarterly estimate of the aggregate quantity of meat articles other than products of Canada which would, in the absence of limitations under the Act, be imported during calendar year 1991 is 1,280 million pounds.

Done at Washington, DC this 12th day of July, 1991.

Edward Madigan,

Secretary of Agriculture.

[FR Doc. 91-17384 Filed 7-19-91; 8:45 am]
BILLING CODE 3410-10-M

Food and Nutrition Service

Food Distribution Program; Value of Donated Foods from July 1, 1991 to June 30, 1992

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the value of donated foods, or where applicable, cash in lieu thereof to be provided in the 1992 school year for each lunch served by schools participating in the National School Lunch Program (NSLP) or by commodity schools and for each lunch and supper served by institutions participating in the Child and Adult Care Food Program.

This notice also announces that the value of agricultural commodities and other foods provided to States during the past school year met the level of assistance authorized under the National School Lunch Act. Thus, there will be no shortfall cash payments to States for the NSLP for the 1991 school year. The annually programmed level of assistance was met in food donations by June 30, 1991.

EFFECTIVE DATE: July 1, 1991.

FOR FURTHER INFORMATION CONTACT: Philip K. Cohen, Chief, Program Administration Branch, Food Distribution Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302-1594 or telephone (703) 756-3660.

SUPPLEMENTAL INFORMATION:

Classification

These programs are listed in the Catalog of Federal Domestic Assistance under No. 10.550, 10.555, 10.558 and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V, and final rule related notice published at 48 FR 29114, June 24, 1983.)

This notice imposes no new reporting or recordkeeping provisions that are subject to Office of Management and Budget review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601-612) and thus is exempt from the provisions of that Act.

National Average Minimum Value of Donated Foods for the Period July 1, 1991 through June 30, 1992

This notice implements mandatory provisions of sections 6(e), 14(f) and 17(h) of the National School Lunch Act (the Act) (42 U.S.C. 1755(e), 1762a(f), and 1766(h)). Section 6(e) of the Act establishes the national average value of donated food assistance to be given to States for each lunch served in NSLP at 11.00 cents per meal. This amount is subject to annual adjustments as of July 1 of each year to reflect changes in the Price Index for Food Used in Schools and Institutions. Section 17(h) of the Act provides that the same value of assistance in donated foods for school lunches shall also be established for lunches and suppers served in the Child and Adult Care Food Program. Notice is hereby given that the national average minimum value of donated foods, or cash in lieu thereof, per lunch under NSLP (7 CFR part 210) and per lunch and supper under the Child and Adult Care Food Program (7 CFR part 228) shall be 14.00 cents for the period July 1, 1991 through June 30, 1992.

The Price Index for Food Used in Schools and Institutions is computed on the basis of five major food components in the Bureau of Labor Statistics' Producer Price Index (cereal and bakery products; meats, poultry and fish; dairy products; processed fruits and vegetables; and fats and oil). Each component is assigned a proportional value using the appropriate relative weight as determined by the Bureau of

Labor Statistics. The value of food assistance is adjusted each July 1 by the annual percentage change in a three-month simple average value of this Price Index for March, April and May. The three-month average of the Price Index decreased by 0.76 percent from 122.88 for March, April and May of 1990 to 121.95 for the same three months in 1991. When computed on the basis of unrounded data and rounded to the nearest one-quarter cent, the resulting national average for the period July 1, 1991 through June 30, 1992 will be 14.00 cents per meal. This is the same as the rate in effect for the past school year.

Section 14(f) of the Act provides that commodity schools shall be eligible to receive donated foods equal in value to the sum of the national average value of donated foods established under section 6(e) of the Act and the national average payment established under section 4 of the Act. Such schools are eligible to receive up to 5 cents of this value in cash for processing and handling expenses related to the use of such foods.

Commodity schools are defined in section 12(d)(7) of the Act as "schools that do not participate in the school lunch program under this Act, but which receive commodities made available by the Secretary for use by such schools in nonprofit lunch programs."

For the 1992 school year, commodity schools shall be eligible to receive donated-food assistance valued at 30.00 cents for each lunch served. This amount is based on the sum of the section 6(e) level of assistance announced in this notice and the adjusted section 4 minimum national average payment factor for school year 1992. The section 4 factor for commodity schools does not include the two cents per lunch increase for schools where 60 percent of the lunches were served in the second preceding year free or at reduced prices, since that increase is applicable only to schools participating in the National School Lunch Program.

Cash in Lieu Payments—Value of Donated Commodities for School Year 1990–1991

Section 6(b) of the Act, as amended, (42 U.S.C. 1755(b)) and the regulations governing cash in lieu of donated foods (7 CFR part 240) require the Secretary of Agriculture by June 1 of each school year to estimate the value of agricultural commodities and other foods that will be delivered to States during that school year. Under the food distribution regulations (7 CFR part 250), these foods are used by schools participating in NSLP. If the estimated value is less than the total level of commodity assistance authorized under section 6(e) of the Act, the Secretary is required by July 1 of that school year to pay to each State educational agency funds equal to the difference between the value of programmed deliveries and the total level of authorized assistance for each State.

During the past school year the adjusted minimum national average value of donated foods or payments of cash in lieu thereof per lunch was 14.00 cents. In accordance with section 6(e) of the Act, the mandated level of commodity assistance was $545,146,224 for school year 1991. The Secretary has determined that at least that amount was available for delivery nationally by June 30, 1991 to meet the mandated level of assistance.

Notice is hereby given, therefore, that no shortfall cash payments will be made for the school year ending June 30, 1991.

Dated: July 16, 1991.

George A. Braley,

Associate Administrator.

[FR Doc. 91–17375 Filed 7–19–91; 8:45 am]

BILLING CODE 3410–30–M

Forest Service

Northern Region; Exemption of Salvage Timber Sale Project from Appeal

AGENCY: Forest Service, USDA.

ACTION: Notification that a salvage timber sale project is exempted from appeals under provisions of 36 CFR part 217.

SUMMARY: This is a notification that the decision to implement the Turkey Salvage Timber Sale in the area of the Turkey Fire on the Lewis and Clark National Forest is exempted from appeal. This is in conformance with provisions of 36 CFR 217.4 (a) (11).

EFFECTIVE DATE: Effective on issuance of the Record of Decision for the Turkey Salvage Timber Sale.

FOR FURTHER INFORMATION CONTACT: John D. (Dale) Gorman, Forest Supervisor, Lewis and Clark National Forest, P.O. Box 869, Great Falls, MT. 59403.

Background

In November 1990, the Turkey Fire burned 31,000 acres of National Forest, Bureau of Land Management, State, and private lands southwest of Stanford, Montana. Over 4,500 acres of the Lewis and Clark National Forest were burned in the Sage Creek/Woodhurst Mountain area of the Little Belt Mountains. Approximately 1,000 acres within the fire perimeter received a patchy burn, light underburn, or were not burned. The remaining 3,500 acres burned hot enough to kill the timber. About 2,940 acres of the burn are suitable for timber production.

In January 1991, an interdisciplinary team was assembled to analyze the opportunity to salvage trees that had been killed or were expected to die as a result of the fire. The team surveyed the burned area to assess the damage that had occurred to the resources and analyze the potential effects of harvesting the killed trees. Their reconnaissance identified a need for prompt harvest.

The timber to be salvaged within the Turkey Fire area consists primarily of ponderosa pine and Douglas fir, with some lodgepole and spruce. Merchantable timber varies in diameter at breast height depending on the species: Ponderosa pine averages 14 inches, Douglas fir and spruce average 11 inches, and lodgepole pine averages 9 inches. Deterioration resulting from "checking" and sap rot will reduce the merchantable volume for sawlogs, especially in the smaller diameter trees. For this reason, the team recognized the need to salvage the timber quickly.

The rate of deterioration due to "checking" and sap rot is dependent on the species and diameter of the tree. Checking was already evident in the lodgepole pine in February 1991. The major reduction in the merchantable volumes for both the lodgepole pine and spruce will occur within the first growing season following the fire.

The ponderosa pine and the Douglas fir are expected to retain their merchantable volumes through the summer of 1991. However, checking and rot will begin to affect smaller diameter ponderosa pine and Douglas fir and the upper portions of the large diameter trees during the 1992 growing season. By the end of the 1992 growing season, merchantable volumes could be reduced as much as 40 percent in the ponderosa pine and Douglas fir. To realize maximum value on the solid volumes before deterioration, harvest should be completed before the summer of 1992.

Additionally, timely harvest will reduce the potential for damage to regenerating seedlings. Tree seed germination will begin during the first season following the fire (summer 1991). To protect the naturally regenerating seedlings, it is desirable to complete harvest activities before the seedlings are large enough to be damaged.

Planned Actions

In January 1991 the Lewis and Clark National Forest Supervisor proposed the salvage harvest of the burned timber within the Turkey Fire area. The environmental analysis of this action was begun in mid-January. Because the Turkey Salvage project analysis includes the Tollgate-Sheep Roadless Area, the analysis was documented in an Environmental Impact Statement. The interdisciplinary team assigned to the analysis began with an initial scoping meeting on January 11, 1991. Six main issues were identified as a result of scoping letters, press releases, and contacts with individuals and State and Federal agencies:

1. Timber Management—To what extent can salvaged timber provide for timber output as directed in the Forest Plan goals and objectives for Management Area B?
2. Wildlife—What are the effects on the existing (post fire) elk hiding cover values and habitat use patterns? What are the effects on the existing habitat management indicator species?
3. Roadless Values—What are the effects of timber harvest and road construction on the roadless and wilderness values in the Tollgate-Sheep Roadless Area?
4. Cost Effectiveness—What is the short-term economic viability of the proposed timber harvest and roading?
5. Soil/Watershed Values—What effects will the proposed timber harvesting and roading have on soil movement and watershed values?
6. Rare Plants—What are the effects on rare plant species?

The interdisciplinary team developed five alternatives to analyze, including the No Action Alternative. The effects of these alternatives are disclosed in an Environmental Impact Statement which was prepared for the proposal. The Proposed Action (Alternative 5) would harvest about 272 acres of sawtimber and 40 acres of post and poles, producing about 1.7 MMBF of timber. Alternative 5 requires 1.4 miles of road construction. About 175 acres of roadless area would be affected. Over 99 percent of the roadless lands within the Tollgate-Sheep Roadless Area would remain roadless. The Proposed Action is within Management Area B, which emphasizes timber management and provides a moderate level of livestock forage production, while minimizing impacts to other resources.

All new roads constructed for the salvage harvest operation will be for that use only, and the roads will be closed to public use during the active sale period. Following the completion of harvest activities, the roads will be physically closed to all motor vehicle travel. Upon completion of the harvest, the roads will be seeded with an appropriate grass/forb mix and fertilized full width to reduce sediment movement, provide wildlife forage, and inhibit noxious weed establishment.

The sale and accompanying work is designed to accomplish the objectives as quickly as possible and minimize the amount of salvage volume lost. To expedite this sale project and the accompanying work, the process according to 36 CFR part 217 is being followed. Under this Regulation the following is exempt from appeal:

> Decisions related to rehabilitation of National Forest System lands and recovery of forest resources resulting from natural disasters or other natural phenomena such as wildfires * * * when the Regional Forester * * * determines and gives notice in the **Federal Register** that good cause exists to exempt such decisions from review under this part.

Upon publication of this notice, The Decision Notice for the Turkey Salvage Timber Sale project will be signed by the Forest Supervisor. Therefore, this project will not be subject to review under 36 CFR part 217.

Dated: July 16, 1991.

John Mumma,

Regional Forester, Northern Region.

[FR Doc. 91-17324 Filed 7-19-91; 8:45 am]

BILLING CODE 3410-11-M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Forum of the Oregon Advisory Committee

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that the Oregon Advisory Committee to the Commission will convene at 8:45 a.m. and adjourn at 5 p.m. on August 12, 1991 at the Red Lion Hotel, Lloyd Center, 1000 NE Multnomah, Portland, Oregon 97232. The Committee will meet to gather data on hate group activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Advisory Committee Chairperson, H.J. Hamilton or Philip Montez, Director of the Western Regional Division (213) 894-3437, (TDD 213/894-0508). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter, should contact the Regional Division office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, July 16, 1991.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 91-17283 Filed 7-19-91; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget (OMB)

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: International Trade Administration.

Title: Follow-up Questionnaire to Evaluate Trade Opportunity Program (TOP) Responses.

Form Numbers: Agency—ITA-4110P OMB—0625-xxxx.

Type of Request: New collection.

Burden: 2,125 respondents; 177 reporting hours.

Average Hours Per Response: 5 minutes.

Needs and Uses: The International Trade Administration's (ITA's) Export Promotion Services and commercial embassy staff use this information for program evaluation and strategic planning of the Trade Opportunity Program (TOP). It enables the staff to: (1) make improvements in the program; (2) better direct the limited resources available to control program quality, (3) determine if policy/procedure adjustments are needed to meet exporter's needs; and (4) administer the TOP program more efficiently and effectively for U.S. exporters.

Affected Public: Businesses or other for profit; small businesses or organizations.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Marshall Mills, 395-7340.

Copies of the above information collection proposal can be obtained by calling or writing DOC Clearance Officer, Edward Michals, (202) 377-3271, Department of Commerce, room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Marshall Mills, OMB Desk Officer, room 3208 New Executive Office Building, Washington, DC 20503.

Dated: July 17, 1991.

Edward Michals,

Departmental Clearance Officer, Office of Management and Organization.

[FR Doc. 91-77386 Filed 7-19-91; 8:45 am]

BILLING CODE 3510-CW-M

International Trade Administration

Certain Circular Welded Carbon Steel Pipes and Tubes from Thailand; Termination of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: On April 18, 1991, the Department of Commerce initiated an administrative review of the antidumping duty order on certain circular welded carbon steel pipes and tubes from Thailand. The Department is not terminating this review.

BACKGROUND: On April 18, 1991, the Department of Commerce published a notice of initiation of administrative review of the antidumping duty order on certain circular welded carbon steel pipes and tubes from Thailand. This notice stated that we would review information submitted by the Saha Thai Steel Pipe Co. Ltd. ("Saha Thai" for the period March 1, 1990 through February 28, 1991. The Standard Pipe Subcommittee of the Committee on Pipe and Tube Imports, petitioners, subsequently withdrew their request for review on June 25, 1991. Since no other interested party has requested an administrative review for this period, the Department is not terminating this review.

EFFECTIVE DATE: July 22, 1991.

FOR FURTHER INFORMATION: Contact Mark Brechtl or Alain Letort, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitutional Avenue, NW., Washington, DC 20230, telephone (202) 377-3793 or telefax (202) 377-1388.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)(1)), and § 353.22(a)(5) of Commerce regulations (19 CFR 353.22(a)(5)).

Dated: July 10, 1991.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 91-17387 Filed 7-19-91; 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

National Marine Fisheries Service; Marine Mammals; Application for Permit; NPA, Glacier Bay National Park and Preserve (P394B)

Notice is hereby given that the Applicant has applied in due form for a Permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

1. *Applicant:* Mr. Mark Schroeder; Chief of Resource Management; Glacier Bay National Park and Preserve; Gustavus, Alaska 99826.

2. *Type of Permit:* Scientific research.

3. *Name and Number of Marine Mammals:* 150 killer whales (*orcinus orca*).

4. *Type of Take:* The applicant proposes to take a maximum of 150 individual killer whales annually by harassment. Individuals may be taken (photographed) more than once to determine seasonal use patterns, pod composition and fidelity, and prey preference. Fifty percent of the animals may be taken up to twice per year. The remaining 50% may be taken as many as 4 times per year depending on an individual's use of the study area.

5. *Location and Duration of Activity:* The study area includes northern southeastern Alaska; specifically Glacier Bay—Icy Strait—Cross Sound. Surveys will be conducted during all months for 5 years.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, 1335 East-West Hwy., room 7234, Silver Spring, Maryland 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the national Marine Fisheries Service.

Documents submitted in connection with the above application are available for review by interested persons in the following offices:

By appointment: Permit Division, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Hwy., suite 7324, Silver Spring, Maryland 20910 (301/427-2289);

Director, Alaska Region, National Marine Fisheries Service, Fed. Bldg., 709 W. 9th Street, Juneau, Alaska 99802 (907/568-7221); and

Director, National Marine Mammal Laboratory, National Marine Fisheries Service, 7600 Sand Point Way, NE BIN C15700, Seattle, Washington 98115 (206/526-4020).

Dated: July 15, 1991.

Nancy Foster,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 91-17306 Filed 7-18-91; 8:45 am]

BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the Philippines

July 16, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: July 23, 1991.

FOR FURTHER INFORMATION CONTACT: Kim-Bang Nguyen, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 535-6735. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, *as amended; section 204 of the* Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limits for certain categories are being adjusted, variously, for swing and special shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tarift

Schedule of the United States (see Federal Register notice 55 FR 50756, published on December 10, 1990). Also see 55 FR 51946, published on December 18, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

July 16, 1991.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 12, 1990, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, and man-made fiber textiles and textile products, produced or manufactured in the Philippines and exported during the twelve-month period which began on January 1, 1991 and extends through December 31, 1991.

Effective on July 23, 1991, you are directed to amend further the directive dated December 12, 1990 to adjust the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and the Philippines:

Category	Adjusted twelve-month limit [1]
Levels in Group I	
347/348	1,042,513 dozen.
643	443,687 numbers.
647/648	610,295 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1990.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-17347 Filed 7-19-91; 8:45 am]

BILLING CODE 3510-DR-F

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List; Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Additions to procurement list.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing the blind or other severely handicapped.

EFFECTIVE DATE: August 19, 1991.

ADDRESSES: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 557-1145.

SUPPLEMENTARY INFORMATION: On April 19, May 3, 17, 24 and 31, 1991, the Committee for Purchase from the Blind and Other Severely Handicapped published notices (56 FR 16075, 20414, 22848, 23876 and 24790) of proposed additions to the Procurement List After consideration of the material presented to it concerning capability of qualified nonprofit agencies to produce the commodities and provide the services at a fair market price and impact of the addition on the current or most recent contractors, the committee has determined that the commodities and services listed below are suitable for procurement by the Federal government under 41 U.S.C. 46-48c and 41 CFR 51-2.6.

I certify that the following actions will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

a. The actions will not result in any additional reporting, recordkeeping or other compliance requirements.

b. The actions will not have a serious economic impact on any contractors for the commodities and services listed.

c. The actions will result in authorizing small entities to produce the commodities and provide the services procurred by the Government.

Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

Bracket, Duct
2840-00-798-0897
Net, Laundry
3510-00-841-8376
3510-00-841-8384
Roll, Tools and Accessories
5140-00-106-5671
Bracket, Angle
5340-01-180-5984
Ion Exchange Compound
6810-00-873-2554
Curtain, Blackout
7230-01-136-7054
7230-00-997-1488
(Remaining Government Requirement)

Services

Janitorial/Custodial, Federal Building and U.S. Courthouse, 750 South Missouri, East St. Louis, Illinois
Janitorial/Grounds Maintenance, West Hill Dam, Uxbridge, Massachusetts

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 91-17232 Filed 7-19-91; 8:45 am]

BILLING CODE 6820-33-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Policy Board Advisory Committee Task Force on Soviet Military

ACTION: Notice of advisory committee meeting.

SUMMARY: The Defense Policy Board Advisory Committee Task Force on Soviet Military will meet in closed session on 13 August 1991 from 0900 until 1600 at 1710 Goodridge Drive, TI-7-2, McLean, Virginia.

The mission of the Defense Policy Board Task Force on Soviet Military is to study developments in the Soviet Union that affect the Soviet Military and make recommendations on policy. At this meeting the Board will hold classified discussions on national security matters.

In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law No. 92-463, as amended [5 U.S.C. App. II, (1982)], it has been determined that this Defense Policy Board Task Force meeting concerns matters listed in 5 U.S.C. 552b(c)(1)(1982), and that accordingly this meeting will be closed to the public.

Dated: July 17, 1991.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-17343 Filed 7-19-91; 8:45 am]

BILLING CODE 3810-01-M

Defense Science Board Task Force on Biological Defense Research Program

ACTION: Cancellation of meeting.

SUMMARY: The meeting notice for the Defense Science Board Task Force on Biological Defense Research Program scheduled for July 22-23, 1991 as published in the Federal Register (Vol.

56, No. 115, Page 27503, Friday, June 14, 1991, FR Doc 91-14141) has been cancelled.

Dated: July 16, 1991.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 91-17344 Filed 7-19-91; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF EDUCATION

Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of Proposed Information Collection Requests.

SUMMARY: The Director, Office of Information Resources Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before August 21, 1991.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok: Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Mary P. Liggett, Department of Education, 400 Maryland Avenue, SW., room 5624, Regional Office Building 3, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Mary P. Liggett (202) 708-5174.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) requires that the Office of management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Acting Director, Office of Information Resources Management, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Mary P. Liggett at the address specified above.

Dated: July 16, 1991.

Mary P. Liggett,

Acting Director, Office of Information Resources Management.

Office of Postsecondary Education

Type of Review: Extension.
Title: Request for Collection Assistance Under Federally Insured Loan Program.
Frequency: On occasion.
Affected Public: State or local governments; businesses or other for-profit; non-profit institutions.
Reporting Burden:
Responses: 1,260.
Burden Hours: 416.
Recordkeeping Burden:
Recordkeepers: 0.
Burden Hours: 0.
Abstract: Lending institutions submit this form to request assistance in obtaining accurate addresses of borrowers under the Federally Insured Student Loan Program. The Department uses this information to obtain the borrower's current address in order for the lender to resume collection activity on the loan.

Office of Postsecondary Education

Type of Review: Extension.
Title: Lender's Manifest for Federally Insured Loans.
Frequency: On occasion.
Affected Public: Businesses or other for-profit.
Reporting Burden:
Responses: 18,000.
Burden Hours: 3,600.
Recordkeeping Burden:
Recordkeepers: 0.
Burden Hours: 0.
Abstract: Lenders report the conversion of a loan to repayment and loans paid in full to the Department. The Department uses the information to track the status of loans under the Federally Insured Student Loan Program.

[FR Doc. 91-17307 Filed 7-19-91; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

[Dockets PP-63 and IE-78-6]

Application to Amend Presidential Permit and Export Authorization

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application.

SUMMARY: Northern States Power has applied to amend Presidential Permit PP-63 and the electricity export authorization contained in Docket No. IE-78-6 in order to add a new substation along the permitted facility and to increase the capability to export electricity to Canada over these facilities.

DATES: Comments, protests or requests to intervene must be submitted on or before August 21, 1991.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Electricity (FE-52), Office of Fuels Programs, Office of Fossil Energy, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585. Docket Number PP-63 or IE-78-6 should appear clearly on the envelope and the document contained therein.

FOR FURTHER INFORMATION CONTACT: Ellen Russell (Program Office) 202-586-9624 or Lise Howe (Program Attorney) 202-586-2900.

SUPPLEMENTARY INFORMATION: The construction, connection, operation, and maintenance of facilities at the international border of the United States for the transmission of electrical energy is prohibited in the absence of a Presidential permit pursuant to Executive Order No. 12038. Exports of electricity from the United States to a foreign country also are regulated and require authorization under section 202(e) of the Federal Power Act.

On June 10, 1991, Northern States Power Company (NSP) applied to amend the Presidential permit in Docket No. PP-63 issued on March 6, 1979. The facilities previously authorized by Presidential Permit PP-63 consist of one 500,000 volt (500 kV) overhead transmission line which crosses the U.S. Canadian international border approximately seven and a half miles west of Warroad in Roseau County, Minnesota, and extends approximately 200 miles south the Canadian border to a substation constructed in the vicinity of Forbes, Minnesota.

NSP proposes to increase the electricity transfer capability of this transmission facility by constructing a

new 80-acre substation on the existing 500-kV line in Roseau County (Section 33 of Lake Township), Minnesota, and upgrading the existing substation at Forbes (Section 1 of Lavell Township), Minnesota. The proposed Roseau substation would contain two 41.5 ohm series capacitor banks. In addition, static VAR compensators (SVC) are to be installed at the existing Forbes Substation. Approximately 5 acres would be added to the 30-acre Forbes site to house the additional equipment. No new lines would enter or exit the facility. NSP proposes to place the new Roseau Substation in service in May 1993 and to complete the upgrading of the Forbes Substation in March 1994.

NSP also has applied to amend its Order in Docket No. IE-78-6 authorizing the export of electrical energy to Canada. As a part of the application NSP supplied a copy of a new NSP and Manitoba Hydro diversity exchange agreement providing for the seasonal exchange agreement providing for the seasonal exchange of 200 megawatts (MW) of electrical power. Manitoba Hydro will make 200 MW available to NSP at all times during the summer season. NSP will make 200 MW available to Manitoba Hydro at all times during the winter season. NSP's need for these amendments is occasioned by this new agreement.

Procedural Matters

Any person desiring to be heard or to protest this application should file a petition to intervene or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the Rules of Practice and Procedures (18 CFR 385.211, 385.214).

Any such petitions and protests should be filed with the DOE on or before the date listed above. Additional copies of such petitions to intervene or protests also should be filed directly with James Alders, Manager, New Facility Permitting, and Michael Connelly, Attorney, Northern States Power Company, 414 Nicollet Mall, Minneapolis, Minnesota 55401.

Pursuant to 18 CFR 385.211, protests and comments will be considered by the DOE in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene under 18 CFR 385.214. Section 385.214 requires that a petition to intervene must state, to the extent known, the position taken by the petitioner and the petitioner's interest in sufficient factual detail to demonstrate either that the petitioner has a right to participate because it is a State Commission; that it has or represents an interest which may be directly affected by the outcome of the proceeding, including any interest as a consumer, customer, competitor, or security holder of a party to the proceeding; or that the petitioner's participation is in the public interest.

A final decision will be made on this application after a determination is made by the DOE that the proposed transaction will not impair the sufficiency of electric supply within the United States or impede or tend to impede the coordination in the public interest of facilities subject to the jurisdiction of the DOE.

Before a Presidential permit or export authorization may be issued or amended, the environmental impacts of the proposed DOE action must be evaluated pursuant to the National Environmental Policy Act of 1969 (NEPA). The NEPA compliance process is a cooperative, non-adversarial process involving members of the public, state governments and the Federal government. The process affords all persons interested in or potentially affected by the environmental consequences of a proposed action an opportunity to present their views, which will be considered in the preparation of the environmental documentation for the proposed action. Intervening and becoming a party to this proceeding will not create any special status for the petitioner with regard to the NEPA process. Should a public proceeding be necessary in order to comply with NEPA, notice of such activities and information on how the public can participate in those activities will be published in the **Federal Register**, local newspapers and public libraries and/or reading rooms in the vicinity of the electric transmission facilities.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above.

Issued in Washington, DC, on July 15, 1991.

Anthony J. Como,

Director, Office of Coal & Electricity; Office of Fuels Programs, Fossil Energy.

[FR Doc. 91-17377 Filed 7-19-91; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ES91-41-000, et al.]

El Paso Electric Co., et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

July 9, 1991

Take notice that the following filings have been made with the Commission:

1. El Paso Electric Company

[Docket No. ES91-41-000]

Take notice that on July 3, 1991, El Paso Electric Company ("Company") filed an application with the Federal Energy Regulatory Commission pursuant to Section 204 of the Federal Power Act seeking authority to negotiate the placement of up to $100 million of notes to be issued by a trust. The trust would be established to finance certain monthly contract payments owed to the Company under a wholesale power sales agreement. The Company would then assign its rights to receive the payments to the trust, whereupon the trust would then sell secured notes of up to $100 million in a negotiated placement to third parties. The notes will be entitled to the benefit of a security interest in all the assets of the trust, and the Company will guarantee the payment of all amounts due under the notes, such guarantee being secured by a lien on your utility property which will be subordinated to the liens of the Company's existing first and second mortgages.

Comment date: August 2, 1991 in accordance with Standard Paragraph E at the end of this notice.

2. South Carolina Electric & Gas Company

[Docket No. ER91-423-000]

July 10, 1991

Take notice that on July 1, 1991, South Carolina Electric & Gas Company (SCE&G) tendered for filing an amendment to its May 2, 1991 filing in this docket.

Comment date: July 24, 1991, in accordance with Standard Paragraph E end of this notice.

3. Arkansas Power & Light Company

[Docket No. ER91-503-000]

July 10, 1991

Take notice that Arkansas Power & Light Company (AP&L) filed an amendment to its filing in Docket No.

ER91-503-000 on July 5, 1991 to respond to requests of FERC Staff and supply additional data.

Comment date: July 24, 1991, in accordance with Standard Paragraph E at the end of this notice.

4. Consumers Power Company

[Docket No. ER91-533-000]

July 11, 1991

Take notice that Consumers Power Company on July 3, 1991 tendered for filing revisions to its Consumers Power Company Service Agreement No. 6 under FERC Electric Tariff, Second Revised Volume No. 1 for service to Edison Sault Electric Company. The revisions, which were provided for in the underlying Agreement, would reflect actual costs of additional facilities rather than the cost projections that were available at the time of the Agreement was entered into. As a result, the monthly Capacity Assurance Factor (CAF) charge would decrease from $67,409 to $59,007. In addition, the cost of paying off the entire CAF amount early would decrease accordingly.

Copies of the filing were served upon Edison Sault and the Michigan Public Service Commission.

Comment date: July 25, 1991, in accordance with Standard Paragraph E at the end of this notice.

5. Florida Power & Light Company

[Docket No. ER91-531-000]

July 11, 1991

Take notice that Florida Power & Light Company, on July 3, 1991, tendered for filing a document entitled Contract For Purchase and Sales of Scheduled Power and Energy Between Florida Power & Light Company and Tampa Electric Company.

Comment date: July 25, 1991, in accordance with Standard Paragraph E at the end of this notice.

6. Northeast Empire Limited Partnership #2

[Docket No. ER91-530-000]

July 11, 1991

Take notice that Northeast Empire Limited Partnership #2 (the "Partnership"), a Maine limited partnership, on July 2, 1991 tendered for filing, pursuant to 18 CFR 35.1 and 35.12, proposed FERC Rate Schedule No. 1, applicable to sales of energy and capacity to Central Maine Power Company ("Central Maine") from biomass waste wood electric generating facility owned and operated by the Partnership in Ashland, Aroostook County, Maine (the "Facility"). The Facility is certified as a qualifying small power production facility within the meaning of sections 201 and 210 of the Public Utility Regulatory Policies Act of 1978 and the regulations promulgated thereunder.

The proposed initial rate is set forth in the Power Purchase Agreement (the "Agreement") which establishes a purchase price based on Central Maine Power's avoided cost and applicable to all electricity delivered by the Partnership to Central Maine Power.

Beginning with the initial date of delivery, as defined in the Agreement, Central Maine Power will pay a capacity and energy charge for electricity delivered by the Partnership to Central Maine Power pursuant to the Agreement. The energy and capacity rates are adjusted in accordance with the provisions of the Agreement.

The Partnership requests waiver of the Federal Energy Regulatory Commission's (the "Commission") notice requirements so that the rate schedule may take effect as of the date of the Partnership's initial delivery to Central Maine Power. The Partnership also seeks waiver of the Commission's requirements for filing changes in its Rate Schedule No. 1 in the event of any change or adjustment in the rates calculated pursuant to the formulas, terms and conditions as set forth in the Agreement.

Additionally, the Partnership seeks waiver of the Commission's regulations regarding cost-of-service documentation, accounting practices, reporting requirements, property dispositions and consolidations, securities issuances or assumptions of liability, the holding of interlocking positions and such other matters as the Commission deems appropriate.

Copies of the instant filing have been served upon Central Maine Power and the Maine Public Utilities Commission.

Comment date: July 25, 1991, in accordance with Standard Paragraph E at the end of this notice.

7. Idaho Power Company

[Docket No. ER91-449-000]

July 11, 1991

Take notice that on June 28, 1991, Idaho Power Company (IPC) tendered for filing an Amendment to Filing regarding the Power Sales Agreement between Idaho Power and the Cities of Azusa, Banning and Colton, California. The Agreement was executed December 26, 1990 and expires September 30, 2009 and provides for the sale of 7 MW of power with associated energy to the three cities. The Amendment modifies the rate methodology used in the Agreement.

IPC has renewed its request for waiver of the notice provisions of § 35.3 of the Commission's regulations in order to permit the Agreement to become effective as of July 1, 1991. Copies of this Amendment were served upon the Idaho Public Utilities Commission, the California Public Utilities Commission and the purchasers under the Agreement.

Comment date: July 25, 1991, in accordance with Standard Paragraph E at the end of this notice.

8. Minnesota Power & Light Company

[Docket No. ER91-532-000]

July 11, 1991

Take notice that on July 3, 1991, Minnesota Power & Light Company (MP&L) tendered for filing as an initial rate schedule a twenty-year Transmission Services Agreement, dated July 1, 1991, with Cyprus Silver Bay Power Corporation (Cyprus) for deliveries of power and energy from Cyprus cogeneration facilities at Silver Bay, Minnesota to the system of Northern States Power Company (Minnesota) (NSP).

Minnesota Power requests waiver of the Commission's notice requirements and an effective date of July 1, 1991.

Copies of the filing have been served on Cyprus, the Minnesota Public Utilities Commission, the Minnesota Department of Public Service, and NSP.

Comment date: July 25, 1991, in accordance with Standard Paragraph E at the end of this notice.

9. Wisconsin Power and Light Company

[Docket No. ER91-523-000]

July 11, 1991.

Take notice that on July 1, 1991, Wisconsin Power and Light Company (WPL) tendered for filing an amendment to a Wholesale Power Agreement dated June 12, 1991, between the Wisconsin Public Power, Inc. and WPL. WPL states that this new Wholesale Power Agreement amendments the previous agreement between the two parties which was first entered June 5, 1989, and later amended March 7, 1990, and designated Rate Schedule No. 152 by the Commission.

The purpose of this new agreement is to revise the points of delivery. Terms of service for this customer will be on a similar basis to the terms of service for other W-3 wholesale customers.

WPL requests that an effective date concurrent with the contract effective date be assigned. WPL states that copies of the agreement and the filing have been provided to the Wisconsin Public Power, Inc. and the Wisconsin Public Service Commission.

Comment date: July 25, 1991, in accordance with Standard Paragraph E at the end of this notice.

10. Kamine Natural Dam Cogen Co., Inc.

[Docket No. QF91-171-000]

July 11, 1991.

On July 3, 1991, Kamine Natural Dam Cogen Co., Inc. tendered for filing an amendment to its filing in this docket.

The amendment clarifies certain technical and ownership organizational structure of the facility.

Comment date: August 12, 1991 in accordance with Standard Paragraph E at the end of this notice.

11. Kamine/Besicorp Beaver Falls L.P.

[Docket No. QF91-172-000]

July 11, 1991.

On July 3, 1991, Kamine/Besicorp Beaver Falls L.P. tendered for filing an amendment to its filing in this docket.

The amendment clarifies certain aspects of the ownership organizational structure of the facility and a change in the applicant's name from Kamine Beaver Falls Cogen Co., Inc. to Kamine/Besicorp Beaver Falls L.P.

Comment date: August 12, 1991, in accordance with Standard Paragraph E at the end of this notice.

12. Oxbow Power of North Tonawanda, New York, Inc.

[Docket No. QF89-111-001]

July 11, 1991.

On June 25, 1991, Oxbow Power of North Tonawanda, New York, Inc. (Applicant) tendered for filing an amendment to its filing in this docket.

The amendment revises the cycle diagram for applicant's proposed cogeneration facility to reflect average annual conditions of operation rather than design conditions.

Comment date: August 12, 1991, in accordance with Standard Paragraph E at the end of this notice.

13. Canal Electric Company

[Docket No. ER89-66-003]

July 12, 1991.

Take notice that on July 5, 1991, Canal Electric Company ("Canal") submitted for filing its compliance report pursuant to the Commission's letter order dated April 23, 1991.

Copies of the tendered filing have been served by Canal upon the Commission's staff, the Massachusetts Attorney General, the Town of Belmont and the Department of Public Utilities.

Comment date: July 29, 1991, in accordance with Standard Paragraph E at the end of this notice.

14. Northern States Power Company (Minnesota Company)

[Docket No. ER91-536-000]

July 12, 1991.

Take notice that on July 5, 1991, Northern States Power Company (Minnesota Company) ("NSP-MN") tendered for filing a Municipal Transmission Service Agreement dated December 18, 1990, between NSP-MN and the City of Blue Earth, Minnesota ("Blue Earth").

The Municipal Transmission Service Agreement is a successor agreement to the Municipal Transmission Service Agreement between NSP-MN and Blue Earth dated September 24, 1984; and the "Temporary Transmission Capacity Agreement" between NSP-MN and Missouri Basin Municipal Power Agency dated August 15, 1988, and approved in Docket No. ER88-343-000.

The Municipal Transmission Service Agreement essentially provides that NSP will wheel power and energy delivered to it by the Western Area Power Administration to the Interstate Power Company for ultimate delivery to Blue Earth. The power in question has been sold by the Missouri Basin Municipal Power Agency to Blue Earth. The rates and charges provided for this service we approved in FERC Docket No. ER88-76 and accepted for filing are on file with the Commission for similar agreements with similarly situated wheeling customers of NSP-MN.

NPS requests the Municipal Transmission Agreement be accepted for filing effective December 20, 1990, and requests waiver of Commission's notice requirements in order for the Agreement to be accepted for filing on that date. NSP requests that the Agreement be accepted as a supplement to Rate Schedule FERC No. 438, the original rate schedule for service to Blue Earth.

Comment date: July 29, 1991, in accordance with Standard Paragraph E at the end of this notice.

15. PacifiCorp Electric Operations

[Docket No. ER91-529-000]

July 12, 1991

Take notice that PacifiCorp Electric Operations ("PacifiCorp"), on July 2, 1991, tendered for filing in accordance with 18 CFR part 35 of the Commission's Rules and Regulations, a Firm Transmission Service Agreement ("Service Agreement") between PacifiCorp Electric Operations ("PacifiCorp") and Sierra Pacific Power Company ("Sierra") dated May 23, 1991 and the Seventh Revised Sheet No. 3.0 superseding Sixth Revised Sheet No. 3.0 (Index of Utilities Executing Service Agreements) of PacifiCorp's FERC Electric Tariff, Original Volume No. 5 ("Tariff").

Under terms of the Agreement, PacifiCorp will provide firm transmission services for Sierra under Service Schedules TS-1 and TS-4 of the Tariff.

PacifiCorp requests, pursuant to 18 CFR 35.11 of the Commission's Rules and Regulations, that a waiver of prior notice be granted and that an effective date of June 1, 1991 be assigned to the Agreement, this date being consistent with the effective date specified in section 2.1 of the Service Agreement.

Copies of this filing were supplied to Sierra Pacific Power Company, the Public Utility Commission of Oregon and the Utah Public Service Commission.

Comment date: July 29, 1991, in accordance with Standard Paragraph E at the end of this notice.

16. Duke Power Company

[Docket No. ER91-526-000]

July 12, 1991

Take notice that on June 26, 1991, Duke Power Company (Duke) tendered for filing a Contract for Economy Energy Transactions between Cajun Electric Power Cooperative, Inc. and Duke Power Company (Agreement). Duke asks that the sixty (60) day notice requirement be waived so that the Agreement may be permitted to become effective on June 6, 1991.

Comment date: July 26, 1991, in accordance with Standard Paragraph E at the end of this notice.

17. PacifiCorp Electric Operations

[Docket No. ER91-528-000]

July 12, 1991

Take notice that PacifiCorp Electric Operations ("PacifiCorp"), on July 2, 1991, tendered for filing in accordance with 18 CFR part 35 of the Commission's Rules and Regulations, Amendment No. 1 ("Amendment") dated May 8, 1991 to the Long-Term Power Sales Agreement ("Agreement") between PacifiCorp and The Arizona Power Pooling Association (APPA") dated March 4, 1991, designated PacifiCorp Rate Schedule, FERC No. 310.

The Amendment revises the assignment provisions of the Agreement.

PacifiCorp requests, pursuant to 18 CFR 35.11 of the Commission's Rules and Regulations, that a waiver of prior notice be granted and that an effective date of May 8, 1991 be assigned to the Amendment, this date corresponding to date the Amendment was executed.

Copies of this filing were supplied to APPA, Arizona Electric Power Cooperative, Inc., City of Mesa, Arizona, Electrical District No. 2 of Pinal County, Arizona, the Public Utility Commission of Oregon and the Utah Public Service Commission.

Comment date: July 29, 1991, in accordance with Standard Paragraph E at the end of this notice.

18. Las Vegas Cogeneration Limited Partnership

Docket No. QF89-251-001]

July 12, 1991

On June 28, 1991, Las Vegas Cogeneration Limited Partnership tendered for filing an amendment to its filing in this docket.

The amendment revises certain information provided in the original filing. The proposed power production capacity has increased from 38 MW to 42 MW and the size of the greenhouse has decreased from 19.2 acres to 12.0 acres. The facility and the greenhouse will not be owned by Las Vegas Cogeneration Limited Partnership.

Comment date: August 12, 1991, in accordance with Standard Paragraph E at the end of this notice.

19. Puget Sound Power & Light Company

[Docket No. ER91-518-000]

July 12, 1991

Take notice that Puget Sound Power & Light Company ("Puget") on July 1, 1991, tendered for filing a proposed Supplement No. 10 to the General Transfer Agreement between Puget and the United States of America, Department of Interior acting by and through the Bonneville Power Administrator ("Bonneville") Contract No. 14-13-001-11487. (Puget sound Power & Light Company Supplement No. 10 to Rate Schedule FPC No. 16.) The proposed Supplement relates to certain transmission service to Tanner Electric at the Ames Lake point of delivery which was previously provided under Contract No. 14-03-65492 between Puget and Bonneville (FPC Rate Schedule No. 19). The proposed change would increase revenue from jurisdictional service under this schedule from $21,481 for the twelve months prior to November 30, 1987 to $134,696 for the twelve months immediately thereafter.

This change in the rate schedule from that formerly effective under Rate Schedule FPC No. 19 is necessary to reflect the costs of providing this transmission service. Puget and Bonneville have agreed upon an effective date for original Supplement No. 10 of November 30, 1987.

Copies of the filing were served upon Bonneville.

Comment date: July 26, 1991, in accordance with Standard Paragraph E at the end of this notice

20. Puget Sound Power & Light Company

[Docket No. ER91-519-000]

July 12, 1991

Take notice that Puget Sound Power & Light Company ("Puget") on July 1, 1991 tendered for filing proposed changes in its Supplement No. 6 to the General Transfer Agreement between Puget and the United States of America, Department of Interior acting by and through the Bonneville Power Administrator ("Bonneville") Contract No. 14-13-001-11487. (Puget Sound Power & Light Company Supplement No. 6 to Rate Schedule FPC No. 16.) The proposed changes would increase revenue from jurisdictional service under this schedule from $18,291 for the twelve months prior to September 30, 1987 to $187,610 for the twelve months immediately thereafter.

The change in the rate schedule is necessary to update changes in cost factors since 1968 and capital investments associated with providing the service. Puget and Bonneville have agreed upon an effective date for the change of 1400 hours on September 30, 1987.

Copies of the filing were served upon Bonneville.

Comment date: July 26, 1991, in accordance with Standard paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17296 Filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

[Project Nos. 5276 and 9706, New York]

Niagara Mohawk Power Corp. and Mechanicville Corp.; Availability of Environmental Assessment

July 15, 1991.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the applications for major license for the proposed Mechanicville Projects located on the Hudson River in Saratoga and Rensselaer Counties, near the towns of Halfmoon and Schaghticoke, about 1.25 miles south of the City of Mechanicville, New York, and has prepared an Environmental Assessment (EA) for the proposed projects. In the EA, the Commission's staff has analyzed the potential environmental impacts of the proposed projects and has concluded that approval of the proposed projects, with appropriate mitigative measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, room 3308, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17297 Filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP91-2392-000, et al.]

Northwest Pipeline Co., et al.; Natural gas certificate filings

Take notice that the following filings have been made with the Commission:

1. Northwest Pipeline Company

[Docket No. CP91-2392-000]

July 9, 1991.

Take notice that on July 2, 1991, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84158-0900, requests authorization in Docket No. CP91-2392-000 under section 7(b) of the Natural Gas Act to abandon all of its jurisdictional gathering system facilities by conveyance to Williams Gas Processing Company (WGP), an affiliated company, and for permission to assign, concurrently with the conveyance of facilities, of all of its non-certificated agreements to provide gathering and processing for third parties, all as more fully set forth in the

application which is on file with the Commission and open to public inspection.

Northwest states that it desires to transfer all of its existing gathering systems, which, it is indicated, include both certificated and non-certificated facilities, to WGP as integrated units. It is indicated that Northwest's gathering systems presently include four processing plants, approximately 90,000 horsepower of field compression and 3,400 miles of pipeline, accessing gas production from over 5,000 wells in the states of New Mexico, Colorado, Wyoming and Utah.

Northwest states that as a result of aggressively implementing the Commission's open-access philosophy, Northwest's merchant role has nearly been extinguished. It is stated that Northwest's current firm sales contract demand is only about 250,000 dt equivalent on natural gas per day as compared to a firm transportation contract demand of about 1,868,000 dt equivalent of natural gas per day. Northwest also indicates that declining sales requirements have necessitated the termination, assignment or restructuring of nearly all of Northwest's gas purchase obligations, leaving Northwest with less than 5,000 Mcf per day of existing system supply accessed by its gathering systems. Northwest states that it no longer needs to own and operate gathering systems in order to access system supply to meet its vanishing merchant obligations.

It is indicated that with nearly all of Northwest's gathering and processing services now being provided on an unbundled basis for producers, marketers and others, competitive pressures have intensified, mandating Northwest to be as responsive as possible to the service and pricing needs of its gathering and processing customers. Northwest states that the downward pressure exerted by market and competitive forces on Northwest's charges for gathering and processing services have created a significant incentive for Northwest to restructure its business operations both to reduce costs of its gathering and processing operations by enhancing efficiency and to increase gathering and processing throughput by enhancing its flexibility to respond productively and expeditiously to the needs of the market.

Comment date: July 30, 1991, in accordance with Standard Paragraph F at the end of this notice.

2. Ringwood Gathering Company

[Docket No. CP91-2340-000]

July 9, 1991.

Take notice that on June 25, 1991, Ringwood Gathering Company (Ringwood), 4828 Loop Central Drive, Houston, Texas 77081, filed in Docket No. CP91-2340-000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon facilities and services that were subject to the Commission's jurisdiction, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Ringwood seeks permission and approval to abandon its entire system and cease all natural gas activities and operations that are currently subject to the Commission's jurisdiction.

Ringwood states that its system is comprised wholly of gathering facilities. Ringwood further states that it would continue to operate its system as a non-jurisdictional gathering facility and to provide gathering service on a non-discriminatory basis to producers and shippers in the vicinity of the Ringwood Field.

Comment date: July 30, 1991, in accordance with Standard Paragraph F at the end of the notice.

3. High Island Offshore System, Great Lakes Gas Transmission Limited Partnership; Great Lakes Gas Transmission Limited partnership; Great Lakes Gas Transmission Limited Partnership

[Docket No's. CP91-2367-000, CP91-2368-000, CP91-2369-000, CP91-2370-000]

July 9, 1991.

Take notice that High Island Offshore System, 500 Renaissance Center, Detroit, Michigan 48243, and Great Lakes Gas Transmission Limited Partnership, Suite 1600, One Woodward Avenue, Detroit, Michigan 48226, (Applicants) filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under the blanket certificates issued by the Commission's Order No. 509 corresponding to the rates, terms and conditions filed in Docket No. RP89-82-000 and in Docket No. CP89-2198-000, respectively, pursuant to section 7 of the natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection. [1]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Comment date: August 23, 1991, in accordance with Standard Paragraph G at the end of this notice.

[1] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual Mcf	Receipt points [1]	Delivery points	Contract date, rate schedule, service type	Related docket start up date
CP91-2367-000 (7-1-91-	Oryx Gas Marketing Limited Partnership (Marketer).	154,200 154,200 56,283,000	OTX	OTX, OLA	4-1-91, IT, Interruptible.	ST91-8696-000, 5-2-91.
CP91-2368-000 (7-1-91-	Northern States Power Company (MN & WI) (LDC).	75,000 75,000 27,375,000	MN	MI	11-1-90, IT, Interruptible.	ST91-8897-000, 5-2-91.
CP91-2369-000 (7-1-91-	DEKALB Energy Company (Producer).	125,000 125,000 45,625,000	MN	MI	10-24-90, IT, Interruptible.	ST91-8899-000, 5-2-91.
CP91-2370-000 (7-1-91)	Brymore Energy Inc. (Marketer)-.	500,000 500,000 182,500,000	MN, MI	MN, MI	10-25-90, IT, Interruptible.	ST91-8898-000 5-2-91.

[1] Offshore Louisiana and offshore Texas are shown as OLA and OTX.

4. Northern Natural Gas Company

[Docket No's. CP91-2396-000, CP91-2397-000, CP91-2398-000, CP91-2399-000]

July 9, 1991.

Take notice that on July 3, 1991, Northern Natural Gas Company (Northern), 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188, filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under its blanket certificate issued in Docket No. CP86-435-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[2]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Northern and is summarized in the attached appendix.

Comment date: August 23, 1991, in accordance with Standard Paragraph G at the end of this notice.

[2] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual MMBTu	Receipt points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-2396-000 (7-3-91)	TexPar Energy, Inc. (Marketer)	100,000 75,000 36,500,000	Various	Various	6-1-91, IT-1, Interruptible	ST91-9107-000, 6-1-91.
CP91-2397-000 (7-3-91)	Semco Energy Services, Inc. (Marketer)	13,500 10,125 4,927,500	Various	MI, IL	6-1-91, IT-1, Interruptible	ST91-9136-000, 6-1-91.
CP91-2398-000 (7-3-91)	NGC Transportation, Inc. (Marketer)	300,000 225,000 109,500,000	Various	TX	6-3-91, IT-1, Interruptible	ST91-9104-000, 6-3-91.
CP91-2399-000 (7-3-91)	Sunrise Energy Company (Marketer)	50,000 37,500 18,250,000	Various	TX	6-1-91, IT-1, Interruptible	ST91-9105-000, 6-1-91.

5. Boston Gas Company

[Docket No. CP91-2315-000]

July 10, 1991.

Take notice that on June 20, 1991, pursuant to Rule 207(a)(2) of the Commission's Rules of Practice and Procedure, Boston Gas Company (Boston Gas), One Beacon Street, Boston, Massachusetts, 02108, filed in Docket No. CP91-2315-000, a request for a declaratory order of the Federal Energy Regulatory Commission (FERC) that by virtue of section 7(c) of the Natural Gas Act, 15 U.S.C. 717(c), certain transportation service provided by Boston Gas to Distrigas of Massachusetts Corporation (DOMAC) pursuant to a firm transportation agreement, as approved by the Massachusetts Department of Public Utilities on July 21, 1988, and certain local distribution facilities used to provide such service, are upon facts not subject to the FERC jurisdiction, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Boston Gas respectfully requests that the FERC issue an order declaring that the transportation service provided pursuant to the firm transportation agreement, is exempt from regulation under the Natural Gas Act. In the alternative, and only if the FERC declines to so order, Boston Gas requests that the FERC waive any concurrent jurisdiction under the Natural Gas Act on the basis of facts present by Boston Gas, indefinitely or until such time as is required for Boston Gas to obtain any necessary section 7(c) authorization.

Comment date: July 31, 1991, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

6. KN Energy, Inc., Arkla Energy Resources, a division of Arkla, Inc.

[Docket Nos. CP91-2406-000 [3], CP91-2413-000]

July 11, 1991.

Take notice that on July 3 and 5, 1991, Applicants filed in the above referenced dockets, prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under their blanket certificates issued pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection and in the attached appendix.

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the docket numbers and initiation dates of the 120-day transactions under § 284.223 of the Commission's Regulations has been provided by the Applicants and is included in the attached appendix.

Applicants state that each of the proposed services would be provided under an executed transportation agreement, and that the Applicants would charge rates and abide by the

[3] These prior notice requests are not consolidated.

terms and conditions of the referenced transportation rate schedule(s).

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

Docket No. (date filed)	Applicant	Shipper name	Peak day,[1] avg, annual	Points of[2]		Start up date, rate schedule	Related[3] dockets
				Receipt	Delivery		
CP91-2406-000 (7-3-91)	KN Energy, Inc. P.O. Box 281304, Lakewood, CO 80228-9304.	Centran Corporation.	50,000Mcf 50,000Mcf 18,250,000Mcf	CO, KS, NE, WY	CO, KS, NE	5-17-91, IT-1, 2 & 3.	CP89-1043-000, ST91-9100-000.
CP91-2413-000 (7-5-91)	Arkla Energy Resources, a division of Arkla, Inc. 26302-2450.	Agrico Chemical Company.	45,000 45,000 16,425,000	AR, LA, OK, TX	AR	11-1-90, FT	CP88-820-000, ST91-8629-000.
		Arkla Energy Marketing Company.	150,000 120,000 43,800,000	AR, LA, OK, TX	AR	4-4-91, IT	CP88-820-000, ST91-8787-000.
		Con-Agra Frozen Foods.	2,900 2,900 1,058,500	AR, LA, OK, TX	AR	11-1-90, FT	CP88-820-000, ST91-8609-000.
		Gaylord Container, Inc.	3,500 3,500 1,277,500	AR, LA, OK, TX	AR	1-1-91, FT	CP88-820-000, ST91-8850-000.
		Arkla Energy Marketing Company.	2,077 2,077 758,105	AR, LA, OK, TX	AR	12-1-90, FT	CP88-820-000, ST91-6268-000.
		Arkla Energy Marketing Company.	8,000 8,000 2,920,000	AR, LA, OK, TX	AR	1-1-91, FT	CP88-820-000, ST91-8372-000.
		Arkla Energy Marketing Company.	10,000 10,000 3,650,000	AR, LA, OK, TX	AR	9-1-90, FT	CP88-820-000, ST91-1198-000.
		Vesta Energy Company.	1,575 1,575 574,875	AR, LA, OK, TX	AR	3-1-91, FT	CP88-820-000, ST91-9094-000.

[1] Quantities are shown in MMBtu unless otherwise noted.
[2] Offshore Louisiana and Offshore Texas are shown as OLA and OTX.
[3] The CP docket corresponds to applicant's blanket transportation certificate. If an ST docket is shown, 120-day transportation service was reported in it.

7. Columbia Gulf Transmission Company

[Docket No. CP91-2420-000, CP91-2421-000, CP91-2422-000]

July 11, 1991.

Take notice that on July 8, 1991, Columbia Gulf Transmission Company (Columbia Gulf), P.O. Box 683, Houston, Texas 77001, filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under its blanket certificate issued in Docket No. CP86-239-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[4]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Columbia Gulf and is summarized in the attached appendix.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

[4] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual MMBtu	Receipt[1] points	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-2420-000 (7-8-91)	NGC Transportation, Inc. (Marketer).	100,000 80,000 29,200,000	OLA	LA	5-30-91, ITS-2, Interruptible.	ST91-8938-000, 6-2-91.
CP91-2421-000 (7-8-91)	Chevron USA, Inc. (Producer).	10,000 8,000 2,920,000	LA	LA	5-1-91, FTS-2, Firm.	ST91-8937-000, 6-1-91.
CP91-2422-000 (7-8-91)	Adobe Gas Marketing Company (Marketer).	100,000 80,000 29,200,000	LA	LA	5-1-91, ITS-2, Interruptible.	ST91-8939-000, 6-1-91.

[1] Offshore Louisiana is shown as OLA.

8. Williams Natural Gas Company

[Docket No. CP91-2407-000]

July 11, 1991.

Take notice that on July 2, 1991, Williams Natural Gas Company (WNG), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket No. CP91-2407-000 a request pursuant to § 157.205 of the Commission's Regulations for authorization to construct and operate a 4-inch tap and measurement instrumentation for the delivery of transportation gas to Golden Gas Energies, Inc. (Golden Gas) for use in an enhanced oil recovery project, under the blanket certificate issued in Docket No. CP82-479-000, and pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

WNG proposes to tap its 6-inch pipeline located in the SW/4 section 11, T27N-R15W, Woods County, Oklahoma, and install measurement instrumentation including flow recorders, a temperature recorder and a continuous gas sampler. It is stated that Golden Gas will install the measurement facilities.

WNG states that it will also utilize these facilities to receive transportation gas from Golden Gas at this location. WNG is not requesting specific receipt authorization in this application since transportation receipt facilities are automatically authorized under WNG's blanket construction certificate.

It is stated that the projected volume of delivery through these new facilities is estimated to be 1,000,000 Mcf annually with 10,000 Mcf delivered on a peak day. According to WNG, the majority of the gas will be delivered from May through August and will have little or not impact on WNG's systemwide peak. It is estimated that the cost of these facilities will be $17,980, which will be reimbursed by Golden Gas.

WNG states that it will utilize its Rate Schedule IT for the transportation delivery and does not have sufficient capacity to render the proposed service without detriment or disadvantage to its other existing customers.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

9. MIGC, Inc.

[Docket No. CP91-2358-000]

July 11, 1991.

Take notice that on June 28, 1991, MIGC, Inc. (MIGC), suite 230, 12200 N. Pecos Street, Denver, Colorado 80234, filed in Docket No. CP91-2358-000 an application with the Commission, pursuant to section 7(b) of the Natural Gas Act, (NGA) for permission and approval to abandon certain natural gas facilities no longer used to provide jurisdictional service, all as more fully set forth in the application which is open to public inspection.

MIGC states that the facilities it proposes to abandon include several compression stations and related appurtenances, inert generation facilities, a gas supply lateral, and certificated gathering lines. Specifically, MIGC has identified the following facilities for abandonment: (1) The Hilight Btu Stabilization and Inert Generation facilities; (2) Oedekoven compressor station; (3) Gas Draw compressor; (4) Jamison Prong compressor and lateral; (5) Gas Draw Junction compressor; and (6) Hines gathering system and compressor. MIGC received authorization June 19, 1970, for the first five facilities in Docket No. CP70-231 (43 FPC 909) and in Docket Nos. CP72-218 (48 FPC 73, July 13, 1972), CP73-254 (50 FPC 787, September 17, 1973), CP81-288-000 (18 FERC ¶62,513, March 24, 1982), and CP82-409-000 (20 FERC ¶62,418, September 2, 1982) for the Hines gathering system. MIGC also states that the proposed abandonment would not affect its ability to provide jurisdictional service to its customers, nor disrupt the production flow into its system.

Comment date: August 1, 1991, in accordance with Standard Paragraph F at the end of this paragraph.

10. Transwestern Pipeline Company; Panhandle Eastern Pipe Line Company

[Docket No. CP91-2374-000, CP91-2375-000, CP91-2377-000, CP91-2378-000]

July 11, 1991.

Take notice that Applicants filed in the respective dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under their blanket certificate pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[6]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Applicants and is summarized in the attached appendix.

Applicants state that each of the proposed services would be provided under an executed transportation agreement, and that Applicants would charge the rates and abide by the terms and conditions of the referenced transportation rate schedules.

Comment date: August 26, 1991, in accordance with standard Paragraph G at the end of this notice.

Applicant: Transwestern Pipeline Company, 1400 Smith Street, P.O. Box 1188, Houston, TX 77251-1188

Blanket Certificate Issued in Docket No.: CP88-133-000

[6] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type shipper)	Peak day, avg, annual.[1]	Point of		Start up date, rate schedule	Related dockets [2]
			Receipt	Delivery		
CP91-2374-000 (07-02-91)	Landmark Gas Corp. (Marketer).	5,000 3,750 1,825,000	AZ, NM, OK, TX	AZ, NM	06-01-91, ITS-1	ST91-9102-000.
CP91-2375-000 (07-02-91)	Ice Brothers, Inc. (Producer).	5,000 3,750 1,825,000	AZ, NM, OK, TX	TX	06-07-91, ITS-1	ST91-9103-000.

[1] Quantities are shown in MMBtu unless otherwise indicated.
[2] If an ST docket is shown, 120-day transportation service was reported in it.

Applicant: Panhandle Eastern Pipe Line Company, P.O. Box 1642, Houston, TX 77251-1642

Blanket Certificate Issued in Docket No. CP86-585-000

Docket No. (date filed)	Shipper name (type shipper)	Peak day, avg, annual [1]	Point of		Start up date, rate schedule	Related dockets [2]
			Receipt	Delivery		
CP91-2377-000 (07-02-91)	Unitfied Natural Gas Group (Marketer).	20,000 20,000 7,300,000	CO, IL, KS, MI, OH, OK, TX.	IL	05-01-91, PT	ST91-8768-000.
CP91-2378-000 (07-02-91)	Enron Gas Marketing Inc. (Marketer).	25,000 25,000 9,125,000	KS	TX	05-01-91, PT	ST91-8771-000.

[1] If an ST docket is shown, 120-day transportation service was reported in it.
[2] Quantities are shown in Dth unless otherwise indicated.

11. Panhandle Eastern Pipe Line Company

[Docket Nos. CP91-2384-000, CP91-2385-000]

July 11, 1991.

Take notice that on July 2, 1991, Panhandle Eastern Pipeline Company (Panhandle), P.O. Box 1642, Houston, Texas 77251-1642, filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under its blanket certificate issued in Docket No. CP86-585-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[6]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by Panhandle and is summarized in the attached appendix.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

[6] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual Dth	Receipt points	Delivery points	Contract data, rate schedule, service type	Related docket, start up date
CP91-2384-000 (7-2-91)	Gastrak Corporation (Marketer).	342,000 342,000 124,830,000	System	Various	6-16-88, PT, Interruptible.	ST91-8770-000, 5-1-91.
CP91-2385-000 (7-2-91)	Caterpillar, Inc. (End user).	15,000 15,000 5,475,000	CO, KS, IL, OK, TX	KS	5-18-89, PT, Interruptible.	ST91-8876-000, 5-1-91.

12. Mississippi River Transmission Corporation

[Docket No. CP91-2366-000]

July 12, 1991.

Take notice that on July 1, 1991, Mississippi River Transmission Corporation (MRT). 9900 Clayton Road, St. Louis, Missouri 63124, filed in Docket No. CP91-2366-0000 an application pursuant to section 7(c) of the Natural Gas Act for authorization to provide a limited-term transportation service with pre-granted abandonment authorization, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

MRT proposes to provide a temporary new service, interruptible transportation within contract demand, to purchasers under MRT's Rate Schedule CD-1. It is stated that the request is made in order to implement a provision in the Stipulation and Agreement filed in its pending rate case in Docket No. RP89-248-000.

MRT states that the proposed service would permit a CD-1 customer, at its option, to transport on an interruptible basis up to 25 percent of such customer's annual system requirements at the non-gas portion of MRT's rate schedule CD-1 sales commodity rate.

MRT states further that it would provide transportation within contract demand service subject to the terms, conditions and provisions of MRT's rate schedule ITS. Such service, it is said, would receive the same scheduling priority as interruptible transportation delivered at maximum rates.

MRT requests pre-granted abandonment of the proposed service, effective April 1, 1994.

Comment date: August 2, 1991, in accordance with Standard Paragraph F at the end of this notice.

13. West Lincoln Natural Gas District, Southern Natural Gas Company

[Docket No. CP87-146-001]

July 12, 1991.

Take notice that on July 2, 1991, West Lincoln Natural Gas District, (West Lincoln), Route 3, Box 646, Brookhaven, Mississippi 39601, and Southern Natural Gas Company, (SNG), P.O. Box 2563, Birmingham, AL 35202-2563, hereinafter collectively referred to as "parties", filed in Docket No. CP87-146-001, a petition to amend the order issued January 21, 1988, in Docket No. CP87-146-000 pursuant to section 7(a) of the Natural Gas Act so as to modify and waive certain provisions of the January order and Southern's Tariff, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Specifically, the parties request a modification of paragraph (D) of the

Commission's order such that West Lincoln will only have to reimburse SNG for $95,500, which is the amount Southern originally estimated as the cost of the distribution facilities. West Lincoln has indicated that it obtained financing for the construction of its distribution facilities, but not the cost of reimbursing SNG for the construction of the measurement facilities which cost is an additional $80,000. West Lincoln has also stated that the difference in the cost for materials when SNG made the initial estimate in March 1987, and when SNG actually performed the construction in February 1991, is the main reason for the increase in the total construction cost. Southern has stated that it believes good cause exist for a limited waiver of the terms described in § 16.5 of its Tariff in order that it be allowed to absorb those amounts over $95,500,000.

Comment date: August 2, 1991, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

14. Tennessee Gas Pipeline Company

[Docket No. CP91-2376-000]

July 12, 1991.

Take notice that on July 2, 1991, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP91-2376-000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations for authorization to provide interruptible transportation service on behalf of Indeck-Yerkes Limited Partnership, an end-user of natural gas, under United's blanket certificate issued in Docket No. CP87-115-000, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Tennessee states that pursuant to a transportation agreement the dated February 1, 1991,[7] as amended on May 21, 1991, it proposes to transport a maximum daily quantity of 6,000 dekatherms, an average day quantity of 6,000 dekatherms, and an annual quantity of 2,190,000 dekatherms, and that service commenced on May 22, 1991, as reported in Docket No. ST91-9182-000, pursuant to § 284.223(a) of the Commission's Regulations.

Tennessee further states that it proposes to transport natural gas from receipt points located in the state of New York to delivery points located in the states of New York and Pennsylvania. The ultimate point of delivery is located in the State of New York.

United further states that existing facilities would be used to provide this transportation service.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

15. Columbia Gas Transmission Corporation

[Docket Nos. CP91-2427-000, CP91-2428-000]

July 12, 1991.

Take notice that on July 9, 1991, Columbia Gas Transmission Corporation (Applicant), P.O. Box 1273, Charleston, West Virginia 25325-1273, filed in the above referenced dockets, prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under its blanket certificate issued in Docket No. CP86-240-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection.[8]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations has been provided by Applicant and is summarized in the attached appendix.

Applicant states that each of the proposed services would be provided under an executed transportation agreement, and that Applicant would charge rates and abide by the terms and conditions of the referenced transportation rate schedule(s).

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

[7] Tennessee was authorized in Docket No. CP91-1797-000 to transport 12,000 dekatherms of natural gas. This authorization proposes to implement an amendment to the transportation agreement to transport an additional 6,000 dekatherms and to add delivery points in the State of New York.

[8] These prior notice requests are not consolidated.

Docket No.[3]	Shipper name.	Peak day,[1] avg. annual	Points of [2]		Start up date, rate schedule, service type	Related docket, contract date
			Receipt	Delivery		
CP91-2427-000 (7-9-91)	Toledo Marriott Portside..	800 640 292,000	KY, NY, OH, PA, WV.....	OH.....	5-3-91, ITS, Interruptible.	ST91-8674-000, 5-1-91.
CP91-2428-000 (7-9-91)	Howell Gas Management Company.	500,000 400,000 182,500,000	KY, OH.....	MD, NJ, NY, OH, PA, VA, WV.	5-1-91, ITS, Interruptible.	ST91-8835-000, 3-25-91.

[1] Quantities are shown in MMBtu.
[2] Offshore Louisiana and Offshore Texas are shown as OLA and OTX.
[3] If an ST docket is shown, 120-day transportation service was reported in it.

16. Florida Gas Transmission Company, Florida Gas Transmission Company, Southern Natural Gas Company, Southern Natural Gas Company, El Paso Natural Gas Company

[Docket No.'s CP91-2400-000, CP91-2401-000, CP91-2402-000 CP91-2403-000, CP91-2405-000]

July 12, 1991.

Take notice that the above referenced companies (Applicants) filed in the respective dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under blanket certificates issued pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection.[9]

Information applicable to each transaction including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day, and annual volumes, and the docket numbers and initiation dates of the 120-day transactions under § 284.223 of the Commission's Regulations has been provided by the Applicants and is included in the attached appendix.

The Applicants also state that each would provide the service for each shipper under an executed transportation agreement, and that the Applicants would charge rates and abide by the terms and conditions of the referenced transportation rate schedules.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

[9] These prior notice requests are not consolidated.

Docket No.	Applicant	Shipper name	Peak day, avg. Annual	Points of		Start up date, rate schedule	Related [2] dockets
				Receipt	Delivery		
CP91-2400-000 7-3-91	Florida Gas Transmission Company, 1400 Smith St., Houston, TX 77002.	St. Joe Natural Gas Company.	([3])	TX, LA, MS, AL, FL, Off LA, Off TX.	FL	6-1-91, PTS-1	CP89-555-000, ST91-9077-000.
CP91-2401-000 7-3-91	Florida Gas Transmission Company, 1400 Smith St., Houston, TX 77002.	St. Joe Natural Gas Company.	2,376 1,782 867,293	TX, LA, MS, AL, FL, Off LA, Off TX.	FL	6-1-91, FTS-1	CP89-555-000, ST91-9079-000.

[1] Quantities are shown in MMBtu unless otherwise indicated.
[2] The CP docket corresponds to applicant's blanket transportation certificate. If an ST docket is shown, 120-day transportation service was reported in it.
[3] Peak Day (phase I) 760, (phase II) 304; Average Day (phase I) 570, (phase II) 228; Annual Basis (phase I) 277,474, (phase II) 110,930.

Docket No.	Applicant	Shipper name	Peak day, avg. Annual	Points of		Start up date, rate schedule	Related [2] dockets
				Receipt	Delivery		
CP91-2402-000 7-3-91	Southern Natural Gas Company, P.O. Box 2563, Birmingham, AL 35202-2563.	Centran Corporation.	4,000 4,000 1,460,000	Off TX, Off LA, TX, LA, MS, AL.	GA	5-7-91, IT	CP88-316-000, ST91-8800-000.
CP91-2403-000 7-3-91	Southern Natural Gas Company, P.O. Box 2563, Birmingham, AL 35202-2563.	Texaco Inc.	100,000 1,000 365,000	Off TX, Off LA, TX, LA, MS, AL.	AL	5-3-91, IT	CP88-316-000, ST91-8798-000.
CP91-2405-000 7-5-91	El Paso Natural Gas Company, P.O. Box 1492, El Paso, TX 79978.	Southern California Edison Company.	500,000 7,000 2,555,000	NM, TX, OK, CO	AZ, NV	6-1-91, T-1	CP88-433-000, ST91-9080-000.

[1] Quantities are shown in MMBtu unless otherwise indicated.
[2] The CP docket corresponds to applicant's blanket transportation certificate. If an ST docket is shown, 120-day transportation service was reported in it.

17. Trunkline Gas Company

[Docket Nos. CP91-2408-000 [10], CP91-2409-000, CP91-2410-000, CP91-2411-000, CP91-2412-000]

July 12, 1991.

Take notice that on July 5, 1991, Trunkline Gas Company (Trunkline), P.O. Box 1642, Houston, Texas 77251-1642, filed in the above referenced dockets, prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 284.223) for authorization to transport natural gas on behalf of various shippers under its blanket certificate issued in Docket No. CP86-586-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection and in the attached appendix.

Information applicable to each transaction including the identity of the shipper, the date of the interruptible transportation agreement between Trunkline and the respective shipper, the contract number of the transportation agreement, function of the shipper, i.e., marketer, producer, intrastate pipeline, etc., the type of transportation service, the appropriate transportation rate schedule, the peak day, average day, and annual volumes, and the docket number and initiation dates of the 120-day transactions under

[10] These prior notice requests are not consolidated.

§ 284.223 of the Commission's Regulations has been provided by Trunkline and is included in the attached appendix.

Trunkline alleges that it would provide the proposed service for each shipper under an executed gas transportation agreement and would charge rates and abide by the terms and conditions of the referenced transportation rate schedules.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

Docket No. trans. agree. (tran. agr. No.)	Shipper name	Shipper's function	Peak day [1] avg. annual	Points of		Start up date rate schedule service type	Related [2] dockets
				Receipt	Delivery		
CP91-2408-000 3-1-89 (T-PLT-1450)	Enron Gas Marketing, Inc..	Marketer	100,000 100,000 36,500,000	Various Existing Points.	TN	5-22-91, PT, Interruptible.	ST91-9005-000.
CP91-2409-000 6-12-86 (T-PLT-0338)	BP Gas, Inc.	Marketer	15,000 15,000 5,475,000	Various Existing Points.	LA	5-25-91, PT, Interruptible.	ST91-9008-000.
CP91-2410-000 9-13-88 (T-PLT-1219)	Enron Gas Marketing, Inc..	Marketer	100,000 100,000 36,500,000	Various Existing Points.	IL	5-24-91, PT, Interruptible.	ST91-9009-000.
CP91-2411-000 5-30-90 (T-PLT-2324)	Exxon Corporation	Producer	150,000 150,000 54,750,000	Various Existing Points.	LA	5-21-91, PT, Interruptible.	ST91-9011-000.
CP91-2412-000 1-5-89 (T-PLT-1352)	Enron Gas Marketing, Inc..	Marketer	50,000 50,000 18,250,000	Various Existing Points.	IL	5-24-91, PT, Interruptible.	ST91-9012-000.

[1] Quantities are shown in MMBtu.
[2] The ST docket indicates that 120-day transportation service was initiated under Section 284.223(a) of the Commission's Regulations.

18. ANR Pipeline Company

[Docket No.'s CP91-2423-000, CP91-2424-000]

July 12, 1991.

Take notice that on July 9, 1991, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243 filed prior notice requests with the Commission in the above-referenced dockets pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to transport natural gas on behalf of various shippers under its blanket certificate issued in Docket No. CP88-532-000, pursuant to section 7 of the NGA, all as more fully set forth in the requests which are open to public inspection.[11]

ANR has provided information applicable to each transaction, including the shipper's identity; the type of transportation service; the appropriate transportation rate schedule; the peak day, average day, and annual volumes; the service initiation date; and related ST docket number of the 120-day transaction under § 284.223 of the Commission's Regulations, as summarized in the appendix.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

[11] These prior notice requests are not consolidated.

Docket No.	Shipper (type)	Peak day, average day, annual Dth	Receipt points [1]	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-2423-000	Tejas Power Corporation (Marketer).	80,000 80,000 29,200,000	LA, OLA, TX, OTX	LA	1-30-89, ITS, Interruptible	ST91-8927, 5-11-91.
CP91-2424-000	CNG Trading Company (Marketer).	50,000 50,000 18,250,000	OLA, TX, OTX	LA	12-19-90, ITS, Interruptible	ST91-8926, 5-9-91.

[1] Offshore Louisiana and offshore Texas are shown as OLA and OTX.

19. Williams Natural Gas Company

[Docket No.'s CP91-2425-000, CP91-2426-000]

July 12, 1991.

Take notice that on July 9, 1991, Williams Natural Gas Company (WNG), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in the above-referenced dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of shippers under its blanket certificate issued in Docket No. CP86-631-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[12]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under § 284.223 of the Commission's Regulations, has been provided by WNG and is summarized in the attached appendix.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

[12] These prior notice requests are not consolidated.

Docket No. (date filed)	Shipper name (type)	Peak day, average day, annual Dth	Receipt points [1]	Delivery points	Contract date, rate schedule, service type	Related docket, start up date
CP91-2425-000 (7-9-91)	Panoak Gas Company, Inc. (Marketer).	2,800 2,800 1,022,000	CO, KS, MO, OK, TX, WY.	KS, OK	5-15-91, ITS Interruptible	ST91-9051-000, 5-17-91.
CP91-2426-000 (7-9-91)	K N Gas Marketing, Inc. (Marketer).	150,000 150,000 54,750,000	CO, KS, MO, OK, TX, WY.	KS, MO, OK, TX, WY	5-15-91, ITS Interruptible	ST91-9337-000, 5-31-91.

20. United Gas Pipe Line Company

[Docket No. CP91-2414-000]

July 12, 1991.

Take notice that on July 8, 1991, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251-1478, filed in Docket No. CP91-2414-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) to construct and operate two taps and related facilities in St. Charles Parish, Louisiana, under United's blanket certificate issued in Docket No. CP82-430-000 pursuant to section 7 of the Natural Gas Act, all as more fully detailed in the application which is on file with the Commission and open to public inspection.

United proposes to install a 6-inch tap and related facilities for deliveries of natural gas to Transamerican Gas Corporation (Transamerican). It is stated that United is authorized to transport up to 100,000 Mcf daily and 36,500,000 Mcf annually on an interruptible basis for Transamerican under prior notice authorization in Docket No. CP91-867-000 and pursuant to United's Rate Schedule ITS.

United also proposes to construct and operate a 2-inch sales tap and related facilities for the sale of up to 5,000 Mcf of natural gas on a daily basis to the Natural Gas Company of Louisiana (NGL) (formerly known as Norco) for resale to St. Charles Elevator under United's Rate Schedule G. It is stated that United received authorization in Docket No. CP71-089 to provide all of NGL's requirements for resale and distribution through NGL's distribution system serving St. Rose, Louisiana. It is asserted that these deliveries would be within NGL's daily entitlement from United.

It is explained that the construction of both taps can be accomplished without detriment to United's other customers. It is stated that United would be reimbursed for the cost of installing the facilities by the customers.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

21. Southern Natural Gas Company

[Docket No. CP91-2404-000]

July 12, 1991.

Take notice that on July 3, 1991, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, AL, 35202-2563, filed a request pursuant to §§ 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act, to construct and operate an additional point of delivery for Atlanta Gas Light Company (Atlanta), an existing customer, all as more fully set forth in the request on file with the Commission and open to public inspection.

Specifically, Southern proposes to construct, install and operate a new meter station and appurtenant facilities related thereto in order to implement the new delivery point (hereinafter referred to as August No. 4) in Jefferson County, Georgia. The total estimated cost of the construction and installation of August No. 4 is $280,300 of which cost Atlanta has agreed to reimburse Southern.

Comment date: August 26, 1991, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17298 filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-194-000]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

July 15, 1991.

Take notice that Algonquin Gas Transmission Company ("Algonquin") on July 9, 1991, tendered for filing as part of its FERC Gas Tariff, Third Revised

Volume No. 1, six copies of First Revised Sheet No. 647.

Algonquin states that section 20.6 of Algonquin's General Terms and Conditions, Third Revised Volume No. 1 is being filed to establish a lien on all natural gas received for transportation or storage to secure payment of any and all charges due to Algonquin from nonpaying customers utilizing Algonquin's pipeline system including its storage facilities. Algonquin states further that section 20.6 also provides that Algonquin may withhold gas from delivery until all unpaid charges have been paid, may sell at public auction gas for which charges remain unpaid after specific notice and demand for payment, and may itself bid for and purchase the gas to be sold.

The proposed effective date of the tariff sheet listed above is July 10, 1991.

Algonquin states that copies of the filing were served on Algonquin's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before July 22, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17299 Filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-193-000]

National Fuel Gas Supply Corp.; Revised Tariff Sheet and Limited Purpose Rate Change Filing

July 15, 1991.

Take notice that on July 9, 1991, National Fuel Gas Supply Corporation (National), pursuant to the requirements of section 4 of the Natural Gas Act (NGA), 15 U.S.C. 717(c), and the Niagara Import Point Projects (NIPPS) Phase II rehearing order, 55 FERC 61,483, issued on June 21, 1991, submitted for filing Second Revised Sheet No. 857 to its FERC Gas Tariff, First Revised Volume No. 2, and a limited purpose rate change.

National states that this revised sheet constitutes changed initial rates (both Demand and Commodity Charges in 5.1) for National's transportation service to Transco Energy Marketing Company (TEMCO) under Rate Schedule X-57, as authorized by the Commission on rehearing of its NIPPS Phase II certificate in Docket No. CP88-94-003. National states further that in the NIPPS Phase II rehearing order the Commission authorized a limited purpose rate case filing to change National's Phase II rates charged to TEMCO to reflect inclusion of any lease expenses, that this filing responds to this authorization for National to file a limited purpose rate change under § 4 of the NGA, and that therefore, the limited rate change should be neither suspended nor made subject to refund.

National also requests a waiver of the thirty-day notice requirement in order to permit this revised tariff sheet, and the changed initial rates stated therein, to become effective as of November 1, 1990, when National began making the lease payments.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before July 22, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17300 Filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ER91-440-000 and ER91-530-000]

Northeast Empire Limited Partnership #1 and Northeast Empire Limited Partnership #2; Filing

July 16, 1991.

Take notice that on July 3, 1991, Northeast Empire Limited Partnership #1 and Northeast Empire Limited Partnership #2 tendered for filing additional information requested by staff in the above referenced dockets.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before July 25, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17301 Filed 7-17-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. GP88-26-002]

Northern Pump Co. (Danner No. A-1 Well); Settlement Proposal

July 15, 1991.

Take notice that on June 28 1991, Hawley & Wright, Inc., Ensign Operating Co. and Williams Natural Gas Company (Williams) submitted a proposed settlement agreement in the above-referenced proceeding. The parties state that the settlement involves the payment of a specified sum by Hawley & Wright to Williams in order to resolve potential refund liability under Commission orders issued herein on December 5, 1990, and March 20, 1991, with respect to deliveries of natural gas from the Danner No. A-1 Well to Williams. In exchange, Williams agrees to withdraw from a pending court review proceeding involving the December 1990 and March 1991 orders. Hawley & Wright in turn agrees not to appeal certain related decisions of the Kansas Corporation Commission. The parties state that the proposed settlement does not resolve the issues in this proceeding as to purchasers other than Williams.

Any person wishing to do so may file comments on the settlement. Such comments should be addressed to the Secretary, Federal Energy Regulatory Commission, 825 North Capital Street, NE., Washington, DC 20426, and should be filed no later than July 24, 1991.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17302 Filed 7-18-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF91-117-000]

Panda-Brandywine, L.P.; Amendment to Filing

July 15, 1991.

On July 10, 1991, Panda-Brandywine, L.P., tendered for filing an amendment to its filing in this docket.

The amendment supplements certain aspects of facility's ownership structure and thermal use.

Any person desiring to be heard or objecting to the granting of qualifying status should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed within 21 days after the date of publication of this notice and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-7303 Filed 7-18-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-195-000]

Texas Eastern Transmission Corp.; Proposed Changes in FERC Gas Tariff

July 15, 1991.

Take notice that Texas Eastern Transmission Corporation (Texas Eastern) on July 9, 1991, tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets with a proposed effective date of July 10, 1991:

Second Revised Sheet No. 416
Fourth Revised Sheet No. 417

Texas Eastern states that section 8.6 of Texas Eastern's General Terms and Conditions, Fifth Revised Volume No. 1 is being filed to establish a lien on all natural gas received for transportation or storage to secure payment of any and all charges due to Texas Eastern for customers utilizing Texas Eastern's pipeline system including its storage facilities. Texas Eastern states further that section 8.6 also provides that Texas Eastern may withhold gas from delivery until all unpaid charges have been paid, may sell at public auction gas for which charges remain unpaid after specific notice and demand for payment, and may itself bid for and purchase the gas to be sold.

Texas Eastern states that copies of the filing were served on Texas Eastern's jurisdictional customers, interested state commissions and all Rate Schedule IT-1 shippers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before July 22, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17304 Filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. RP87-33-012 and TA88-1-43-005]

Williams Natural Gas Co.; Report of Refunds

July 15, 1991.

Take notice that Williams Natural Gas Company (WNG), on June 28, 1991, tendered for filing with the Federal Energy Regulatory Commission (Commission) its supplemental summary report of refunds reflecting additional funds due to Kansas Power and Light Company, Missouri Public Service Company and City Utilities of Springfield for the period of January 1, 1988 through December 21, 1989. No other sales customers and no transportation customers were affected by this revision of WNG's report of refunds filed February 27, 1991.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214 (1989)). All such protests should be filed on or before July 22, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Persons that are already parties to the proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-17305 Filed 7-19-91; 8:45 am]

BILLING CODE 6717-01-M

Office of Hearings and Appeals

Cases Filed During the Week of May 17 through May 24, 1991

During the Week of May 17 through May 24, 1991, the appeals and applications for exception or other relief listed in the appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: July 16, 1991.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of May 17 through May 24, 1991]

Date	Name and location of applicant	Case No.	Type of submission
5/20/91	Murphy/Eastern Oil Company, Inc. and Imperial Oil Co., Inc., Tampa, FL.	RR309-2 RR309-3	Request for Modification/Rescission in the Murphy refund Proceeding. If granted: The January 22, 1991 Decision and Order (Case Nos. RF309-1102 and RF309-1103) issued to Eastern Oil Company and Imperial Oil Company would be modified regarding the firms' Applications for Refund submitted in the Murphy refund proceeding.
5/20/91	The Oak Ridger, Oak Ridge, TN	LFA-0123	Appeal of an Information Request Denial. If granted: The Oak Ridger would receive access to DOE information.
5/21/91	Gulf/T.L. Baker, Washington, DC	RR300-84	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The May 1, 1990 Decision and Order (Case No. RF300-5488) issued to T.L. Baker regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/John S. Causey Dist., Inc., Washington, DC	RR300-73	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The July 27, 1989 Decision and Order (Case No. RF300-5327) issued to John S. Causey Dist., Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Dempsey P. Albutton, Washington, DC	RR300-82	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The July 24, 1989 Decision and Order (Case No. RF300-5323) issued to Dempsey P. Albutton regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/F.S. Winterle & Son, Inc., Washington, DC	RR300-76	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The January 25, 1990 Decision and Order (Case No. RF300-9301) issued to F.S. Winterle & Son, Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Oleum Corporation, Washington, DC	RR300-80	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The January 4, 1989 Decision and Order (Case No. RF300-6912) issued to Oleum Corporation regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Peterson Petroleum, Inc., Washington, DC	RR300-79	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The March 2, 1990 Decision and Order (Case No. RF300-10986) issued to Peterson Petroleum, Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Petroleum Products of South Georgia, Inc., Washington, DC.	RR300-77	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The May 1, 1989 Decision and Order (Case No. RF300-5326) issued to Petroleum Products of South Georgia, Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/McAdory Oil Company, Washington, DC	RR300-87	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The August 11, 1989 Decision and Order (Case No. RF300-5321) issued to McAdory Oil Company regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Morris Petroleum, Inc., Washington, DC	RR300-75	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The February 27, 1989 Decision and Order (Case No. RF300-2200) issued to Morris Petroleum, Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Saxon Oil Company, Inc., Washington, DC	RR300-83	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The June 18, 1990 Decision and Order (Case No. RF300-9370) issued to Saxon Oil Company, Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Trenton Lehigh Coal and Oil Company, Washington, DC.	RR300-78	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The December 21, 1988 Decision and Order (Case No. RF300-5381) issued to Trenton Lehigh Coal and Oil Company regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Joe Lee Smith, Distr., Washington, DC	RR300-86	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The July 27, 1989 Decision and Order issued to Joe Lee Smith, Distr., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Smith Oil Company, Washington, DC	RR300-85	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The June 29, 1990 Decision and Order (Case No. RF300-8760) issued to Smith Oil Company regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Yandle Oil Company, Washington, DC	RR300-81	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The May 8, 1989 Decision and Order (Case No. RF300-6500) issued to Yandle Oil Company regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.

Date	Name and location of applicant	Case No.	Type of submission
5/21/91	Gulf/James M. Walker, Jr., Washington, DC	RR300-74	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The August 11, 1989 Decision and Order (Case No. RF300-5485) issued to James M. Walker, Jr., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	Gulf/Wyche Oil Company, Inc., Washington, DC	RR300-72	Request for Modification/Rescission in the Gulf refund proceeding. If granted: The November 29, 1989 Decision and Order (Case No. RF300-5919) issued to Wyche Oil Company, Inc., regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
5/21/91	James L. Schwab, Spokane, WA	LFA-0124	Appeal of an Information Request Denial. If granted: The Freedom of Information Request Denial issued by the Office of Administrative Services would be rescinded, and James L. Schwab would receive access to DOE information.
5/21/91	Western Construction, Inc., Boise, ID	LFA-0125	Appeal of an Information Request Denial. If granted: The May 9, 1991 Freedom of Information Request Denial issued by the Albuquerque Operations Office would be rescinded, and Western Construction, Inc., would receive access to a complete abstract of the results on MK-Ferguson REP No. Low-91-02.
5/22/91	Bernard Hanft, Forest Hills, NY	LFA-0126	Appeal of an Information Request Denial. If granted: The May 14, 1991 Freedom of Information Request Denial issued by the Office of Coal Conversion would be rescinded, and Bernard Hanft would receive access to a complete report of specified documents which relate to the conversion of coal to gaseous and liquid fuels and the demonstration of such processes.

Refund Applications Received

Date received	Name of refund proceeding/name of refund application	Case No.
5/17/91 thru 5/24/91	Texaco Refund Applications Received.	RF321-15307 thru RF321-15451
5/17/91 thru 5/24/91	Crude Oil Refund Applications Received.	RF272-89343 thru RF272-89358
5/20/91	City of Austin	RF326-274
5/20/91	Hunt Petroleum Corporation.	RF326-275
5/20/91	Speedway Petroleum Co., Inc.	RF300-16769
5/20/91	Aluminum Company of America.	RF300-16770
5/20/91	John H. Bentley & Son, Inc.	RF300-16771
5/20/91	Linus Smith	RF335-5
5/20/91	Marion Co. R-II Sch Dist.	RF335-6
5/20/91	Fair Play R-II Schools.	RF335-7
5/20/91	Tesoro Petroleum Distrb. Corp.	RF322-4
5/20/91	Falstaff Brewing Corp.	RF336-4
5/21/91	James M. Myers	RF335-8
5/21/91	Richard Parsons	RF335-9
5/21/91	Richard P. Stewart.	RF335-10
5/21/91	Koch Refining Co.	RF322-5
5/21/91	City Public Service.	RF326-276
5/21/91	Hoosier Oil, Inc	RF334-9

Refund Applications Received—Continued

Date received	Name of refund proceeding/name of refund application	Case No.
5/22/91	Tesoro Petroleum Distrb. Corp.	RF333-10
5/22/91	Larry L. Minnix	RF335-11
5/22/91	Jack Purvis	RF335-12
5/22/91	El Paso Electric Company.	RF326-277
5/22/91	John Royster	RC272-119
5/23/91	Hershel Burdette	RF300-16772
5/23/91	Thom Zinson & McWhite.	RF300-16773
5/23/91	Ram Fuel Corp	RF300-16774
5/23/91	Ram Fuel Corp	RF300-16775
5/23/91	Ottawa Park Gulf	RF300-16776
5/23/91	Franklin Park Gulf.	RF300-16777
5/23/91	Wilhelm Pkg. Store.	RF335-13
5/23/91	G. M. Truck & Bus Group.	RF336-5
5/23/91	Racetrac Petroleum, Inc.	RF326-278

[FR Doc. 91-17378 Filed 7-19-91; 8:45 am]
BILLING CODE 6450-01-M

Cases Filed During the Week of May 24 Through May 31, 1991

During the week of May 24 through May 31, 1991, the appeals and applications for exception or other relief listed in the appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: July 16, 1991.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of May 24 through May 31, 1991]

Date	Name and Location of Applicant	Case No.	Type of submission
May 24, 1991	Salomon, Inc., Washington, DC	LEF-0033	Implementation of special refund procedures. If granted: The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 CFR, Part 205, Subpart V, in connection with the September 17, 1990 Consent Order entered into with Salomon, Inc.
May 28, 1991	Glen Milner, Seattle, WA	LFA-0127	Appeal of an information request denial. If granted: The May 1, 1991 Freedom of Information Request Denial issued by the Albuquerque Operations Office would be rescinded, and Glen Milner would receive information regarding the shipment of Trident nuclear warheads and a related waiver of fee charges for all documents released.
Do	Texaco/Louis Diloreto, Ossining, NY	RD321-64	Request for modification/rescission in the Texaco refund proceeding. If granted: The April 8, 1991 Decision and Order (Case No. RF321-6779) issued to Louis Diloreto regarding the firm's Application for Refund submitted in the Texaco refund proceeding would be modified.
May 29, 1991	Gulf/Five Points Gulf, Hardin, KY	RR300-88	Request for modification/rescission in the Gulf refund proceeding. If granted: The May 21, 1991 Decision and Order (Case No. RF300-16717) issued to Five Points Gulf regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.
Do	West Point Pepperell, Inc., LaGrange, GA	RR272-77	Request for modification/rescission in the crude oil refund proceeding. If granted: The January 31, 1991 Decision and Order (Case No. RF272-23786) issued to West Point Pepperell, Inc., regarding the firm's Application for Refund submitted in the crude oil refund proceeding would be modified.
May 30, 1991	Bernard Hanft, Forest Hills, NY	LFA-0128	Appeal of an information request denial. If granted: The May 4, 1991 Freedom of Information Request Denial issued by the Office of Coal Conversion would be rescinded, and Bernard Hanft would receive access to documents which relate to the conversion of coal to gaseous and liquid fuels and the demonstration of such processes.
Do	Texaco/Dave's Texaco, New Orleans, LA	RR321-65	Request for modification/rescission in the Texaco refund proceeding. If granted: The September 11, 1991 Decision and Order (Case Nos. RF321-4000 and RF321-6469) issued to Dave's Texaco regarding the firm's Application for Refund submitted in the Texaco refund proceeding would be modified.

REFUND APPLICATIONS RECEIVED

Date received	Name of refund proceeding/name of refund application	Case No.
5/24/91 thru 5/31/91.	Texaco refund applications received.	RF321-15452 thru RF321-15525.
5/24/91 thru 5/31/91.	Crude oil refund applications received.	RF272-89359 thru RF272-89377.
5/24/91 thru 5/31/91.	Gulf Oil refund applications received.	RF272-16778 thru RF272-16947.
5/24/91	Home Oil Co., Inc.	RF330-20.
5/24/91	T.L. Dickerson	RF330-21.
5/24/91	Fisher's Fuel, Inc	RF326-279.
5/24/91	DBA Bettles Lodge.	RF326-280.
5/24/91	Green County Sch Dist.	RF272-120.
5/28/91	F.S. Services, Inc.	RF322-6.
5/28/91	Ray W. Martin	RF335-4.
5/28/91	Niebrugge Oil Co.	RF330-22.
5/28/91	Brittany Dyeing-Printing Corp.	RF336-6.
5/28/91	EG&G Automotive Research.	RF326-281.
5/28/91	Green County Highway Dept.	RF272-121.
5/29/91	Ross Fuel Co	RF304-12290.
5/29/91	Miller Oil	RF304-12291.
5/29/91	Swan Oil	RF304-12292

REFUND APPLICATIONS RECEIVED—Continued

Date received	Name of refund proceeding/name of refund application	Case No.
5/29/91	William R. Gift, Inc.	RF304-12293.
5/29/91	Heston S. Swartley Trans. Co.	RF304-12294.
5/29/91	Mullis Petroleum Products.	RF304-12295.
5/29/91	Norris Supply Co., Inc.	RF304-12296.
5/29/91	Shindeldecker Oil Co.	RF304-12297.
5/29/91	Little Oil Co	RF304-12298.
5/29/91	Alex Oil of Texas	RF304-12299.
5/29/91	Cortez Gas Co	RF304-12300.
5/29/91	William Moehrle	RF272-122.
5/30/91	Crystal Petroleum	RF315-2950.
5/30/91	Baron-Huot Oil Co.	RF330-23.
5/30/91	Apex Oil Company.	RF326-282.
5/31/91	Shell Oil Co	RF336-7.
5/31/91	A.C. Tift Jr	RF315-10147.
5/31/91	Giant Industries, Inc.	RF326-283.
5/31/91	Tauber Oil Company.	RF326-284.
5/31/91	Fletcher Oil Company.	RF326-285.

REFUND APPLICATIONS RECEIVED—Continued

Date received	Name of refund proceeding/name of refund application	Case No.
5/31/91	Kirschner Brothers Oil Company.	RF326-286.
5/31/91	Nu Way Distributing Company.	RF326-287.
5/31/91	Thrift Distributors, Inc.	RF326-288.
5/31/91	Swifty Distributors, Inc.	RF326-289.
5/31/91	Economy Oil Co	RF326-290.
5/31/91	Susser Petroleum Company.	RF326-291.
5/31/91	Wayne E. McKay Oil Co.	RF330-24.
5/31/91	Stafford Oil Co., Inc.	RF330-25.
5/31/91	Barbour Bros. Inc.	RF330-26.
5/31/91	Midland Sixty-Six Oil Co.	RF330-27.
5/31/91	Jack Walstad Oil Co., Inc.	RF330-28.

[FR Doc. 91-17379 Filed 7-19-91; 8:45 am]

BILLING CODE 6450-01-M

Cases Filed During the Week of June 14 Through June 21, 1991

During the week of June 14 through June 21, 1991, the appeal and applications for other relief listed in the appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: July 16, 1991.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of June 14 through June 21, 1991]

Date	Name and location of applicant	Case No.	Type of submission
June 14, 1991	Amoco I, Amoco II, Vickers, Coline, Nat'l Helium, Perry Gas/Michigan, Lansing, MI.	RM21-244, RM251-245, RM1-246, RM2-247, RM3-248, RM183-249	Request for modification/rescission in the Amoco I, Amoco II, Vickers, Coline, Nat'l Helium & Perry Gas second stage refund proceeding. If granted: The March 21, 1984 and December 18, 1987 Decision and Order (Case Nos. RQ21-47, RQ251-396, RQ1-397, RQ2-398, RQ3-399 & RQ183-400) would be modified regarding the state's application for refund submitted in the Amoco I, Amoco II, Vickers, Coline, Nat'l Helium & Perry Gas second stage refund proceeding.
Do	Charles T. McCaffrey, Inglewood, CA	LFA-0132	Appeal of an Information Request Denial. If Granted: The June 14, 1991 Freedom of Information Request Denial issued by the Office of Inspector General would be rescinded, and Charles T. McCaffrey would receive access to requested information relating to the distribution of funds attendant to the DOE/Garrett Enrichment Systems "Personnel Retention Program."
June 20, 1991	Belridge/Utah, Amoco I/Utah, Amoco II/Utah, Salt Lake City, UT.	RM8-250, RM251-251, RM21-252	Request for modification/rescission in the Belridge, Amoco I and Amoco II refund proceedings. If granted: The June 4, 1985 and March 21, 1988 Decision and Order (Case Nos. RQ8-157, RQ251-419 and RQ21-418) would be modified regarding the state's application for refund submitted in the Belridge, Amoco I and Amoco II second stage refund proceeding.

Date received	Name of refund proceeding/name of refund application	Case No.
5/31/91	Arizona Public Service Co.	RF327-6.
6/17/91	S.W. Livingston Co. R-I School.	RF335-25.
6/17/91	Rosetta Pratcher	RF335-26.
6/17/91	Martin Oil Co	FR333-14.
6/17/91	Olympia Oil & Wood Products.	RF334-10.
6/17/91	Tauber Oil Co	RF338-4.
6/17/91	Sullivan's ARCO of Long Meadow.	RF304-12305.
6/18/91	Hazel B. Boland	RF335-27.
6/19/91	Hackensack Water Co.	RF336-12.
6/19/91	Powell C. McCall	RF307-10189.
6/20/91	Palo Pinto/Utah	RQ5-568.
6/20/91	Vickers/Utah	RQ1-569.
6/20/91	Nat'l Helium/ Utah.	RQ3-570.
6/20/91	Coline/Utah	RQ2-571.
6/20/91	Amoco II/Utah	RQ251-572.
6/20/91	Consolidated Edison Company.	RF336-13.
6/20/91	Rosa Dykes	RF335-28.
6/20/91	George H. Wohlt	RF335-29.
6/21/91	Acme Car Wash	RF304-12306.
6/21/91	Plymouth LP Gas Corporation.	RF139-207.
6/14/91 thru 6/21/91.	Texaco refund applications received.	RF321-15740 thru RF321-15779.
6/14/91 thru 6/21/91.	Crude oil refund applications received.	RF272-89421 thru RF272-89427.
6/14/91 thru 6/21/91.	Gulf oil refund applications received.	RF300-17054 thru RF300-17080.

Issuance of Decisions and Orders, Office of Hearings and Appeals During the Week of June 10 Through June 14, 1991

During the week of June 10 through June 14, 1991 the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the office of Hearings and Appeals.

Appeals

James L. Schwab, 6/11/91, LFA-0120

James L. Schwab filed an Appeal from a partial denial by the Department of Energy's (DOE) Nevada Operations Office (NOO) of a Request for Information which he had submitted under the Freedom of Information Act (the FOIA). In considering the Appeal, the DOE found that a document was properly withheld under Exemption 6 and that the NOO conducted an adequate search for documents which were responsive to Schwab's request. The Appeal was accordingly denied.

James L. Schwab, 6/14/91, LFA-0124

James L. Schwab filed an Appeal from a determination issued by the Office of Administrative Services (OAS) in which OAS informed Mr. Schwab that there were no documents responsive to a portion of his Freedom of Information Act (the FOIA) request. In considering the Appeal, the DOE found that OAS's original search was adequate under the FOIA and reasonably calculated to uncover responsive documents. The Appeal was therefore denied.

Request for Exception

Colonial Gas Company, 6/12/91, LEE-0016

Colonial Gas Company (Colonial) filed an Application for Exception in which the firm sought to be relieved of the requirement to file Form EIA-857, entitled "Monthly Report of Natural Gas Purchases and Deliveries to Consumers." In reviewing the request, the DOE found that Colonial would not suffer a hardship, inequity or unfair

distribution of burdens by fulfilling its reporting obligation. Accordingly, exception relief was denied.

Refund Applications

East River Corporation, Milford Management Corporation, Parkchester Management Corporation, Woods Management Corporation, 6/13/91, RR272-73, RR272-74, RR272-75, RR272-76

The DOE issued a Decision and Order concerning a Motion for Reconsideration filed by a consortium of U.S. States requesting the reversal of four previous Decisions which granted refunds to realty management companies in New York City. The States contended that the four Decisions were inconsistent with two other Decisions, in which realty management companies had been partially denied refunds. Upon reconsideration, the DOE found that the Decisions were not inconsistent as the two companies had been denied refunds because their claims were based in part on purchases for which they stated they had been previously compensated. The States' Motion was therefore denied.

Empire Gas Corporation/Bill Gilmore, et al., 6/10/91, RF 335-4, et al.

The DOE issued a Decision and Order concerning five Applications for Refund filed in the Empire Gas Corporation special refund proceeding. All of the applicants are end users who adequately documented the volume of their Empire purchases. The refunds granted in this decision totalled $490, including $337 in principal and $153 in accrued interest.

School District of Philadelphia, 6/14/91, RF272-29777

On June 14, 1991, the DOE issued a Decision and Order granting an Application for Refund filed in the crude oil special refund proceeding by the School District of Philadelphia (School District). A group of utilities, transporters and manufacturers (the commenters) objected to the application filed by the School District and provided evidence concerning the presumption of end-user injury in the cases of state and federal government claimants. While the city of Philadelphia has waived the rights of itself and its "affiliates" under its "control" to subpart V Crude Oil Refunds from the OHA in order to receive a refund from the Refiners' Escrow established by the Stripper Well Settlement Agreement, the School District established that it is a district legal entity separate from the city. The Decision and Order determined that since it is not under the potential control of Philadelphia, the Waiver and Release submitted by the City of Philadelphia does not bind the School District. The Decision and Order concluded that the School District was entitled to receive its full allocable share of the crude oil monies and granted it a $68,736 refund.

Shell Oil Company/AHCO, Inc., AHCO, Inc., 6/11/91, RF315-2566, RF315-2567

The DOE issued a Decision and Order denying the refund application filed by Amos F. Humphrey of AHCO, Inc. in the Shell Oil Company special refund proceeding. The DOE determined that Mr. Humphrey's right to a refund had been transferred when he sold the stock of his firm in 1983. Accordingly, the applications of AHCO, Inc. were denied.

Shell Oil Company/D&B Oil Company, D&B Oil Company, 6/11/91, RF315-4230, RF315-4231

The DOE issued a Decision and Order denying the refund application filed by Broach Oil Company on behalf of D&B Oil Company in the Shell Oil Company special refund proceeding. Broach had purchased the assets of D&B in 1981. The DOE determined that Broach was not eligible to receive D&B's refund because it had purchased only certain assets, rather than all the outstanding capital stock of D&B. The DOE also noted that Broach's purchase of D&B's Shell jobber contract did not transfer D&B's right to a refund to Broach. Accordingly, we denied the two applications.

Walker Construction Company, 6/11/91, RF272-77362

The Department of Energy issued a Decision and Order granting a refund from the crude oil overcharge funds to Walker Construction Company (Walker), a company that purchased "AC 10," "AC 20," "Primer L," "SS1H," and "RS-2." The DOE determined that AC 10 and AC 20 are liquid asphalts and that Primer L, SS1H, and RS-2 are asphalt emulsions. The DOE further established that both liquid asphalt and asphalt emulsion are covered products. However, because Walker purchased asphalt emulsions in a 60/40 blend of liquid asphalt and water, 40 percent of Walker's asphalt emulsion purchases were deducted from Walker's claim. The refund granted to Walker is $6,282.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Akeley School District.	RF272-78756	06/12/91
Atlantic Richfield Co./Henry Rumpel Arco *et al.*	RF304-11914	06/12/91
Atlantic Richfield Co./Lane's Atlantic *et al.*	RF304-4234	06/12/91
Atlantic Richfield Co./Lex Arco *et al.*	RF304-4941	06/12/91
Atlantic Richfield Co./Manny's Auto Repair *et al.*	RF304-4572	06/14/91
Atlantic Richfield Co./Oliver Motor Service, Inc *et al.*	RF304-9410	06/10/91
Atlantic Richfield Co./Pennsylvania Power & Light Co.	RF304-816	06/11/91
Bedford School District.	RF272-81355	06/10/91
Boston University	RF272-64978	06/14/91
Clark Bros. *et al*	RF272-58449	06/12/91
Community of Sisters of St Dominic *et al.*	RF272-77363	06/10/91
Farmers Union Oil Company.	RF272-47458	06/11/91
Gulf Oil Corporation/ Adams Gulf Servicenter.	RF300-8164	06/12/91
Gulf Oil Corporation/ Cornell Oil Co. Inc.	RF300-6395	06/10/91
Gulf Oil Corporation/ Henley's Gulf.	RF300-6612	06/10/91
Gulf Oil Corporation/ Holiday Gulf *et al.*	RF300-11512	06/11/91
Gulf Oil Corporation/ International Aviation.	RF300-11207	06/10/91
Gulf Oil Corporation/ Interstate Gulf Service.	RF272-6791	06/10/91
Housing Authority of Baltimore City.	RF272-40751	06/13/91
Illinois Dept. of Energy and Natural Resources.	RF272-65524	06/14/91
Joseph B. Koppelman.	RF272-50557	06/13/91
Lasco Shipping Company.	RF272-2889	06/11/91
Lasco Shipping Company.	RD272-2889	
Mass Transit Administration of Baltimore, Maryland.	RF272-20560	06/11/91
Murphy Oil Corp./ Kennedy Oil Co., Inc.	RF309-1105	06/11/91
Phillip Morris Companies, Inc.	RF272-23536,	06/11/91
Phillip Morris Companies, Inc.	RF272-23536,	
General Foods Corporation,.	RF272-61989,	
General Foods Corporation,.	RF272-61989,	
Atlantic Gelatin	RF272-62399	
Ray Carroll County Grain Growers, Inc.	RF272-47974	06/13/91
Shell Oil Company/ Crystal Petroleum Company.	RF315-2950	06/13/91
Shell Oil Company/ Julio C. Rios *et al.*	RF315-9014	06/14/91
Shell Oil Company/ Salinas Valley Oil Company.	RF315-4481	06/14/91
Texaco Inc./Barrie Hood, Inc. *et al.*	RF321-7910	06/12/91
Texaco Inc./ Cortellessa's Texaco Service *et al*	RF321-76	06/10/91

Texaco Inc./Glass Oil Co. *et al.*	RF321-7922	06/12/91
Texaco Inc./Max Hansonl.	RF321-8265	06/14/91
Max Hansonl	RF321-8266	
Max Hansonl	RF321-8267	
Max Hansonl	RF321-8268	
Texaco Inc./OIE Motor Co. *et al.*	RF321-7213	06/11/91
Texaco Inc./ Outboard Motors Inc. *et al.*	RF321-7001	06/13/91
Texaco Inc./Tower Sales, Inc. *et al.*	RF321-2292	06/14/91
Texaco Inc./Vestavia Texaco *et al.*	RF321-1453	06/13/91
Windom School District.	RF272-78797	06/12/91

Dismissals

The following submissions were dismissed:

Name	Case No.
Admiral Cruises, Inc	RD272-63889
Admiral Cruises, Inc	RD272-23225
American Hoist & Derrick Co	RD272-23005
Bernard Hanft	LFA-0128
C&J Service Station	RF300-12303
Centerville Texaco	RF321-2219
City of Fayetteville, NC	RF272-86536
City of Ventnor City, NJ	RF272-89270
Clallam County, WA	RF272-88411
Dale's Texaco #2	RF321-169
Erwin Motor Company	RF321-12577
Eugene Hrabal & Sons	RF272-45098
Fred Phillips Texaco	RF321-11940
Independent School District No. 62.	RF272-81953
Jim's Texaco Service	RF321-10088
Kaplan of Farrington and W.H.S., Inc.	RF272-78349
Keyport Parkway Service Garage	RF304-12171
Lake Geneva-Genoa UHS School District.	RF272-87533
Mason County School District	RF272-80478
Quickfill of North Texas	RF304-3467
Quickfill of North Texas	RF304-3470
Quickfill of North Texas	RF304-3471
Quickfill of North Texas	RF304-3474
Quickfill of North Texas	RF304-3466
Quickfill of North Texas	RF304-3476
Quickfill of North Texas	RF304-3487
Quickfill of North Texas	RF304-3550
Quickfill of North Texas	RF304-3551
Quickfill of North Texas	RF304-3552
Quickfill of North Texas	RF304-3563
Quickfill of North Texas	RF304-3465
Quickfill of North Texas	RF304-3464
Quickfill of North Texas	RF304-3463
Quickfill of North Texas	RF304-3462
Quickfill of North Texas	RF304-3461
Quickfill of North Texas	RF304-3459
Quickfill of North Texas	RF304-3458
Quickfill of North Texas	RF304-3468
Quickfill of North Texas	RF304-3469
Quickfill of North Texas	RF304-3475
Santa Rosa ISD	RF272-89082
Steve Thompson Trucking, Inc	RF304-9416
Steve Thompson Trucking, Inc	RF304-3457
Thomas J. Fallis	RF321-15355
Tommy's Texaco	RF321-1816
Vermillion County, IN	RF272-88972
Village of Sands Point, NY	RF272-89282
William L. L. Ratliff	RF300-12630

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, room 1E-234, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, Monday through Friday, between the hours of 1 p.m. and 5 p.m., except federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: July 12, 1991.

Richard W. Dugan,

Acting Director, Office of Hearings and Appeals.

[FR Doc. 91-17382 Filed 7-19-91; 8:45 am]

BILLING CODE 6450-01-M

Issuance of Decisions and Orders During the Week of June 3 Through June 7, 1991

During the week of June 3 through June 7, 1991 the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Appeals

B.M.F. Enterprises, 6/5/91, *LFA-0116*

B.M.F. Enterprises (BMF) filed an Appeal from a determination issued by the Oak Ridge Operations Office (ORO) of the Department of Energy (DOE). The determination denied a Request for Information which BMF submitted under the Freedom of Information Act (FOIA). BMF requested the evaluation scores assigned to bidders for a subcontract for cafeteria and vending services at the DOE's Portsmouth Gaseous Diffusion Plant. In considering the Appeal, the DOE found that the ORO had correctly determined that the evaluation scores were not agency records and were not subject to release pursuant to the FOIA. Accordingly, BMF's Appeal was denied.

Energy Research Corporation, 6/6/91, *LFA-0122*

Energy Research Corporation filed an Appeal from a determination issued by the Chicago Operations Office (Chicago) concerning a request for information which it submitted under the Freedom of Information Act (FOIA). Chicago withheld portions of a letter contract and an entire winning proposal pursuant to Exemptions 3 and 4 of the FOIA. The DOE determined that the withheld information was confidential under Exemption 4. The DOE also determined that the information was protected from unauthorized disclosure by the Office of Federal Procurement Policy Act, 41 U.S.C.A. 423 (1991). Since this statute prohibits disclosure of certain information, the DOE determined that it is a proper Exemption 3 statute.

Kirkpatrick & Lockhart, 6/5/91, *LFA-0118*

Kirkpatrick and Lockhart (K & L) filed an Appeal from a determination issued to it by the Office of the Assistant General Counsel for Intellectual Property (OAGC) of the Department of Energy (DOE). In that determination, OAGC denied the existence of DOE records responsive to a request K & L had filed pursuant to the Freedom of Information Act (FOIA). Although documents responsive to K & L's request apparently exist in the custody of a DOE contractor, OAGC deemed those documents to be contractor-owned and thus not "agency records" which may be subject to public disclosure under the FOIA. OAGC issued that determination informally by telephone, however, rather than in writing, as required by 10 CFR 1004.5(b) and 1004.7(b). Because OHA could not evaluate K & L's Appeal in the absence of full, written statement of reasons for OAGC's decision, OHA remanded the matter to OAGC for issuance of a written determination in compliance with the FOIA regulations.

Linda Loiacano, 6/5/91, LFA-0121

Linda Loiacano filed an Appeal from a determination issued by the Department of Energy's Oak Ridge Office. The Oak Ridge Office determined that none of the documents requested by Ms. Loiacano under the Freedom of Information Act (FOIA) could be released pursuant to Exemptions 5 and 6. In considering the appeal, the DOE found that the justification for withholding the requested information was adequate under the FOIA. The Appeal was, therefore, denied.

Refund Applications

Alaska Department of Transportation and Public Facilities, 6/5/91, RF272-65526

The DOE issued a Decision and Order concerning an Application for Refund filed by the Alaska Department of Transportation and Public Facilities in the subpart V crude oil refund proceeding. The Applicant's claim was based on purchases of refined petroleum products used in the operation of the Alaska state government. The total volume approved in the Decision and Order is $127,752,097 gallons of refined petroleum products and the total refund granted is $102,202.

Atlantic Richfield Company/Eastern Air Lines, Inc., 6/4/91, RF304-2970

The DOE issued a Decision and Other in the ARCO special refund proceeding concerning an Application for Refund filed by Eastern Air Lines, Inc. (Eastern). Eastern purchased 26,131,572 gallons of jet fuel from ARCO during 1973 and 1974. However, Eastern was involved in a legal action against ARCO under Section 210 of the Economic Stabilization Act in which Eastern alleged that ARCO had overcharged it for purchases of 22,455,178 gallons of jet fuel during the period November 1, 1973 through October 23, 1974. Eastern ultimately received a judgment under which it recovered damages in the amount of $179,160. Consequently, the DOE determined that inquiry relating to Eastern's purchases of 22,455,178 gallons of jet fuel no longer existed. A refund was granted for the remaining 3,676,394 gallons, yielding $3,956 ($2,702 in principal an $1,254 in interest). Because Eastern entered into bankruptcy after filing this Application, the refund was sent to the Trustee for Eastern Air Lines, Inc.

Atlantic Richfield Company/Irco Corporation, Lanes Corporation, 6/6/91, RF304–7573, RF304–7578

The DOE issued a Decision and Order concerning Applications for Refund filed by the Irco Corporation and Lanes Corporation in the Atlantic Richfield Company (ARCO) special refund proceeding. The firms submitted cost banks and market price data which indicated that they were forced to absorb ARCO's alleged overcharges. Therefore, the firms have shown that they were injured, to the full extent of their volumetric allocations of the consent order fund, by ARCO's alleged overcharges. After examining the firms' applications and supporting documentation, the DOE concluded that the firms should receive a refund totaling $43,946, representing $29,949 in principal and $13,997 in interest.

City of Los Angeles, Department of Water and Power, 6/4/91, RR272–59

The DOE granted a Motion for Reconsideration filed by the City of Los Angeles Department of Water and Power (DWP), requesting a reevaluation of the denial of its Application for Refund in the subpart V crude oil overcharge refund proceeding. In an earlier determination the DOE found that DWP was an affiliate of the City of Los Angeles. The DOE further found that the right of DWP to a crude oil overcharge refund had been waived by the City of Los Angeles, when the City received a refund from the escrow fund established for crude oil refiners in the Stripper Well proceeding. In considering the Motion, the DOE found that DWP was operationally and financially independent from the City, and was therefore not an "affiliate" of the City for purposes of the crude oil overcharge refund proceeding. The DOE therefore found that the City's waiver should not be applied to DWP. Accordingly, DWP was granted a refund of $3,426,198.

Greene County School District, Greene County Highway Department 6/4/91, RC272–120, RC272–121

The Department of Energy issued a Decision and Order rescinding *Lee County School District No. 1*, No. RF272–78786 (May 7, 1991), with regard to Greene County School District, Case No. RF272–78833, and *Greenville Transit Authority*, No. RF272–76003 (August 6, 1990), with regard to Greene County Highway Department, Case No. RF272–76206. The DOE determined that purchases made by Greene County School District and Greene County Highway Department were included in the claim previously granted to Greene County, Case No. RF272–14322 in *Greene County*, No. RF272–14322 (January 18, 1989). Therefore, the DOE did not disburse the funds approved for Greene County School District and required Petroleum Funds, Inc., the filing service handling Greene County Highway Department's claim, to remit the sum of $718.

Macoupin County Highway Department, et al., 6/4/91, RF272–64006, et al.

The Department of Energy (DOE) has issued a Decision and Order that grants five Applications for Refund filed in the subpart V crude oil refund proceeding. The applicants filed for refunds based on their purchases of refined petroleum product during the period August 19, 1973 through January 27, 1981. To determine the number of gallons of product one applicant purchased, the DOE converted the Applicant's oil, gasoline, and asphalt purchases from dollars to gallons using an Energy Information Administration resource. The total refund amount granted to the five applicants was $26,448.

Payette County, 6/6/91, RF272–72886

The Department of Energy (DOE) issued a Decision and Order concerning an Application for Refund filed by Payette County. Payette County had requested a refund from crude oil overcharge funds based on its purchases of refined petroleum products during the period August 19, 1973 through January 27, 1981. The information submitted by Payette County was not complete. The OHA was unable to contact Payette County to obtain the necessary information. Therefore, because Payette County had not submitted information upon which the OHA could either evaluate its application or calculate a refund amount, the Application of Payette County was dismissed.

Shell Oil Company/Genetin & Walizer Shell, 6/3/91, RF315–4284

The DOE issued a Decision and Order denying the refund application filed by Joseph Genetin of Genetin & Walizer Shell in the Shell Oil Company special refund proceeding. The DOE determined that Mr. Genetin's right to a refund had been transferred when he sold his interest in the station to his partner, Mr. Walizer, in 1977. We stated that although potential refunds were not explicitly mentioned in the partnership dissolution agreement, the language clearly indicated the intent of the partners to transfer to Mr. Walizer all assets, including those, such as refunds which were unknown and unenumerated at the time of the sale. Accordingly, we denied Mr. Genetin's application.

Texaco Inc./Tri-Valley Distributing, Inc., Cook Oil Co., 4-Way Service, D.E. Schmutz, Barlow Oil, 4-Way Service, 6/5/91 RF321–2763, RF321–2764, RF321–2765, RF321–2766, RF321–6699, RF321–9269

The DOE issued a Decision and Order concerning six Applications for Refund filed in the Texaco Inc. special refund proceeding by resellers of Texaco petroleum products during the refund period. Scott Cook, a vice-president of Tri-Valley Distributing, Inc. (Tri-Valley), a Texaco distributor, filed five refund applications based on purchases made during the refund period by Tri-Valley, its affiliate, Cook Oil Co. (Cook Oil) and three subsidiaries: 4-Way Service (4-Way), D.E. Schmutz d/b/a Desco, Inc. (Desco) and Barlow Oil (Barlow). In addition, the DOE received an application filed by Vivian Birdzell, requesting a refund based on purchases that she and her husband made as the owners of 4-Way during the refund period (Case No. RF321–9269). Tri-Valley purchased 4-Way, Desco and Barlow after the end of the consent order period. Mr. Cook was unable to prove that the previous owners of 4-Way and Desco transferred their rights to possible refunds in the sale of these firms to Tri-Valley. Therefore, Tri-Valley's applications on behalf of these firms were denied. Mrs. Birdzell's application, Case No. RF321–9269, was approved. The DOE found, however, that Tri-Valley had acquired Barlow's stock and was therefore eligible for a refund for purchases made by Barlow. Accordingly, Tri-Valley's application on

behalf of Barlow was approved. In addition, the DOE approved Mr. Cook's applications on behalf of Tri-Valley and Cook. Since the DOE has previously determined that the purchase volumes of affiliated firms should be combined, Mr. Cook's applications were considered together in determining the amount of the refund to which Tri-Valley (on behalf of itself and Barlow) and Cook Oil are entitled. Tri-Valley was granted a refund of $14,257, Cook Oil was granted a refund of $10,390, and Mrs. Birdzell was granted a refund of $22,437.

Refund Applications

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

American Diesel Services, American Diesel Services.	RF272-72271, RD272-72271	06/06/91
Atlantic Richfield Co./Frank's Richfield Service *et al.*	RF304-2742	06/03/91
Enron Corporation, Enron Corporation.	RF272-27189, RD 272-27189	06/05/91
Gulf Oil Corp./ Brookside Store *et al.*	RF300-12703	06/05/91
Gulf Oil Corp./Miles Oil Company, Inc.	RF300-11206	06/06/91
Gulf Oil Corp./ Mountain Empire Oil Company.	RF300-8409	06/03/91
Gulf Oil Corp./ Thompson's Gulf Service *et al.*	RF300-10916	06/06/91
Gulf Oil Corp./Young Oil Company, Inc.	RF300-11182	06/04/91
Monarch Cruise Lines, Inc. *et al.*,.	RF272-65436,	06/04/91
Monarch Cruise Lines, Inc.,.	RD272-65436,	
Monarch Cruise Lines, Inc.	RD272-65441	
NCR Corporation,.....	RF272-22388,	06/06/91
NCR Corporation.....	RD272-22388	
Northwestern Steel and Wire Company.	RF272-64610	06/03/91
Northwestern Steel and Wire Company.	RD272-64610	
Oilfield Pipe & Supply, Inc.	RF272-71283	06/03/91
Public Service Company of Indiana, Inc.	RF272-64241	06/04/91
Sawyer County Highway Department *et al.*	RF272-67800	06/06/91
Shell Oil Company/ Budget Oil Co., Inc. *et al.*	RF315-704	06/05/91
Shell Oil Company/ Christ Ziavras *et al.*	RF315-6552	06/03/91
Shell Oil Company/ DBW Enterprises, Inc, F&W Center Texaco, *et al.*	RF315-4872	06/06/91
Willis Shaw Express	RF272-517	06/06/91
Wrenshall School District.	RF272-78717	06/05/91

Dismissals

The following submissions were dismissed:

Name	Case No.
Absecon Gulf Service	RF300-12461
Alleghany County, VA	RF272-87875
Archer Air Conditioning Company, Inc.	RF321-15173
Arnold Transit Company	RF272-89242
Barrow Oil Company	RF300-16028
Bay City, TX	RF272-87852
Borough of Olyphant, PA	RF272-87855
Borough of Phoenixville, PA	RF272-88968
Bradley School District 61	RF272-87609
Cashua State Service Station	RF300-16047
Chicksaw County, MS	RF272-86698
Chief Oil Company	RF321-10909
Choctaw County, OK	RF272-87775
City Gulf Service	RF300-15911
City of Dodge City, KS	RF272-88628
City of Ellisville, MO	RF272-88612
City of Goshen, IN	RF272-88422
City of Lacrescent, MN	RF272-88352
City of Lawrence, KS	RF272-88341
City of New Brunswick, NJ	RF272-89071
City of Othello, WA	RF272-89070
City of Perham, MN	RF272-86711
City of Prairie Village, KS	RF272-88846
City of Rancho Palos Verdes, California.	RF272-88559
City of Washington, IL	RF272-89055
City/Village of Green Hills, Ohio	RF272-88426
Cloutierville Mini-Mart	RF300-7048
Collier County, FL	RF272-87766
Community Hospital	RF272-88715
Cook Construction Co., Inc	RF272-86644
Corinth School District	RF272-86848
Darrell's Gulf	RF300-14510
Depies Oil Co	RF321-8742
Doyle Lumber Company	RF321-15129
Escalon Unified	RF272-89059
Florence County, WI	RF272-89220
Frank E. Hurtte	RF321-15137
Gary Guey	RF300-16448
Gilboa Conesville Central School	RF272-89218
Gothard's Gulf	RF300-11827
Grace Distribution Service, Inc	RF304-9413
Greene County School District	RF272-67872
Greene County, MO	RF272-89048
Greenville Area School District	RF272-80332
Henderson Air Base Texaco	RF321-6112
Hollow Rock-Bruceton School District.	RF272-78721
Hunterdon County, NJ	RF272-87768
Isham's Holiday Gulf	RF300-11887
Jerry Juneau c/o J&J	RF300-7058
Keeneyville School District 20	RF272-87614
Knight's Gulf	RF300-16125
Lee Hy Paving	RF272-64964
Lunenburg County, VA	RF272-87771
Mack's Gulf	RF300-16196
Marathon Gulf	RF300-16106
Matteson Elementary School District 162.	RF272-89212
Morgan County, UT	RF272-87888
Mound Bayou Public Schools	RF272-81847
Municipality of Murrysville, Pennsylvania.	RF272-88420
Nelson County, VA	RF272-87889
New Albany Public Schools	RF272-79972
Noris Decanter Gulf	RF300-6617
Orleans County, NY	RF272-87709
Peeler's Service Station	RF300-16194
Pennsylvania Power & Light Co	RF272-64901
Phillips County, KS	RF272-88974
Primerica Corporation	RF300-11089
Raul's Texaco Service Station	RF321-8943
RHEA County Highway Dept	RF272-86755
Rocksprings ISD	RF272-87605
Saint Peter School District	RF272-78754
Santa Barbara County, CA	RF272-88984
Schuyler County, NY	RF272-89050
Shelby County, IN	RF272-87887
Sikeston R VI	RF272-88851
Snowden's Texaco	RF321-14975
State of Nevada	RF272-74239
Stone County Schools	RF272-86757
Sydney Pyles Plumbing and Heating Co., Inc.	RF321-15238
The Martin Bower Company	RF304-9417
Town of Rayville, LA	RF272-82631
Township of South Whitehall, Pennsylvania.	RF272-89073
Union County, FL	RF272-87907
Village of Kings Point, NY	RF272-88355
W.E. Jersey & Sons, Inc	RF300-13984
Western Cartage, Inc	RF321-15164
Win's Gulf Service Station	RF300-15839

Copies of the full text of these decisions and orders are available in the Public Reference room of the Office of hearings and Appeals, room 1E-234, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, Monday and Friday, between the hours of 1 p.m. and 5 p.m., except federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: July 16, 1991.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 91-17381 Filed 7-19-91; 8:45 am]

BILLING CODE 6450-01-M

Western Area Power Administration

Floodplain/Wetlands Involvement Determination for the Hoyt Substation Additions; Morgan County, CO

AGENCY: Western Area Power Administration, DOE.

ACTION: Statement of findings.

SUMMARY: The Western Area Power Administration (Western) proposes to rebuild and expand the existing Hoyt Substation in Morgan County, Colorado, in order to increase service reliability and enhance system flexibility. According to the Federal Emergency Management Agency floodplain maps, the proposed action is located in a floodplain and is, therefore, a "floodplain action" as defined by DOE regulations in 10 CFR 1022.4(j). Executive Order 11988, "Floodplain Management," states that if an agency proposes to allow an action to be located in a floodplain, the agency is required to consider alternatives to

avoid adverse effects in the floodplains. The proposed action does not effect any wetlands. Therefore, Executive Order 11990, "Protection of Wetlands" does not apply.

Construction within the floodplain by means of the proposed action would be unavoidable as there are no practicable alternatives available. Alternatives to the proposed action, including the no action alternative and a new site alternative are presented in the floodplain/wetlands assessment. Implementation of these alternatives would have a similar or greater impact on the floodplain than that anticipated from the proposed substation expansion.

Expansion of the existing Hoyt Substation by means of the proposed action is unavoidable unless the substation is moved from its present location to a new site out of the floodplain. However, the benefits of such action are extremely questionable in that the relocation would: (1) Be extremely expensive; (2) still require a crossing(s) of, or construction within, the floodplain by extension of other existing line now entering the substation from the north and west; and (3) predictably result in even greater overall environmental consequences.

Western would design the base level of the substation expansion to be at least 2 feet above the elevation of the 100-year flood. The proposed action complies with applicable State and local floodplain protection standards. Surface disturbance associated with the expansion of the existing substation and the physical presence of the existing and enlarged substation during operation are not expected to alter the floodplain storage volume or cause a local increase in the flood stage. No watercourse would be altered or relocated as a result of the project.

FOR FURTHER INFORMATION OR COPIES OF THE FLOODPLAIN/WETLANDS ASSESSMENT CONTACT:

Mr. Stephen A. Fausett, Area Manager, Loveland Area Office, Western Area Power Administration, P.O. Box 3900, Loveland, CO 80539-3003, (303) 490-7200.

Gary W. Frey, Director, Division of Environmental Affairs, Western Area Power Administration, P.O. Box 3402, Golden, CO 80401-3398, (303) 231-1527.

Issued at Golden, Colorado, June 13, 1991.

William H Clagett,

Administrator.

[FR Doc 91-17383 Filed 7-19-91; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3976-6]

Open Meeting on August 8, 1991: Technology Innovation and Economics Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT)

Under Public Law 92463 (The Federal Advisory Committee Act), EPA gives notice of the first meeting of the Industrial Pollution Prevention Focus Group of the Technology Innovation and Economics (TIE) Committee. The TIE Committee is a standing committee of the National Advisory Council for Environmental Policy and Technology (NACEPT), an advisory committee to the Administrator of the EPA. The meeting will convene August 8, from 8:30 a.m. to 5 p.m. at the Washington Court Hotel, 525 New Jersey Avenue, NW., Washington, DC 20001.

The Industrial Pollution Prevention Focus Group is examining methods by which pollution prevention can be encouraged through effluent guidelines. The TIE Committee believes that among the most important barriers to the implementation of pollution prevention concepts and programs are disincentives inadvertently built into the standard setting process, including the effluent guidelines and the process for developing new effluent guidelines. The Focus Group seeks to involve industry, academia, environmental groups, and all levels of government in the incorporation of pollution prevention into the Agency's Office of Water effluent guidelines decision making process and into the effort to spread the pollution prevention ethic.

The Focus Group will act as an "Ongoing Forum" for the Industrial Pollution Prevention Project and will review the products of at least the following projects for the Agency:

- Re-engineer the effluent guidelines process.
- Examine the use of technology transfer in the effluent guidelines program.
- Examine how to influence consumer behavior.
- Product labeling as a tool to influence industrial and consumer behavior.
- Industry awards as mechanisms to encourage the use pollution approaches to environmental management.

The August 8 meeting will be open to the public. Written comments will be received and reviewed by the Focus Group. Additional information may be obtained from David R. Berg or Morris Altschuler at the above address, by calling 202-382-3153, or by written request sent by fax 202-245-3882.

Dated: July 15, 1991.

Robert Hardaker,

NACEPT Designated Federal Official.

[FR Doc. 91-17371 Filed 7-19-91; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51766; FRL 3937-2]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice announces receipt of 32 such PMNs and provides a summary of each.

DATES: Close of review periods:

P 91-793, 91-794, July 13, 1991.

P 91-1141, September 15, 1991.

P 91-1175, 91-1176, 91-1177, September 28, 1991.

P 91-1178, 91-1179, 91-1180, 91-1181, 91-1182, 91-1183, 91-1184, 91-1185, 91-1186, 91-1187, September 29, 1991.

P 91-1188, 91-1189, 91-1190, 91-1191, 91-1192, 91-1193, 91-1194, September 30, 1991.

P 91-1195, October 2, 1991.

P 91-1196, September 29, 1991.

P 91-1197, 91-1198, 91-1199, October 2, 1991.

P 91-1201, 91-1202, September 30, 1991.

P 91-1203, 91-1204, October 5, 1991.

Written comments by:

P 91-793, 91-794, June 13, 1991.

P 91-1141, August 16, 1991.

P 91-1175, 91-1176, 91-1177, August 29, 1991.

P 91-1178, 91-1179, 91-1180, 91-1181, 91-1182, 91-1183, 91-1184, 91-1185, 91-1186, 91-1187, August 30, 1991.

P 91-1188, 91-1189, 91-1190, 91-1191, 91-1192, 91-1193, 91-1194, August 31, 1991.

P 91-1195, September 2, 1991.

P 91-1196, August 30, 1991.

P 91-1197, 91-1198, 91-1199, September 2, 1991.

P 91-1201, 91-1202, August 31, 1991.
P 91-1203, 91-1204, September 5, 1991.

ADDRESSES: Written comments, identified by the document control number "(OPTS-51766)" and the specific PMN number should be sent to: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., rm. L-100, Washington, DC, 20460, (202) 382-3532.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, rm. EB-44, 401 M St., SW., Washington, DC 20460 (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the TSCA Public Docket Office Room NE-G004 at the above address between 8 a.m. and noon and 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays.

P 91-793

Manufacturer. Moore Business Forms, Inc.

Chemical. (S) Bisphenol A diglycidyl ether; bis-(3-aminopropyl)-methylamine; isophorone diamine.

Use/Production. (S) Carbonless paper coating. Prod. range: 106,236-123,234 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 2.0 g/kg species (Rat). Eye irritation: slight species (Rabbit). Skin irritation: negligible species (Rabbit). Skin sensitization: negative species (Guinea pig).

P 91-794

Manufacturer. Moore Business Forms, Inc.

Chemical. (G) Polyurea-epoxy composite polymer.

Use/Production. (S) Carbonless copy paper coating. Prod. range: 11,776-13,413 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5.0 g/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit). Skin sensitization: negative species (Guinea pig).

P 91-1141

Manufacturer. Angus Chemical Company.

Chemical. (S) 7*A*-Hydroxymethylidhydro-3,5-bis(1-methylethyl)-1*H*,3*H*,5*H*,-oxazolo (3,4-cloxazole).

Use/Production. (G) Open, nondispersive. Prod. range: Confidential.

P 91-1175

Importer. USR Optonix, Inc.

Chemical. (S) Yttrium oxide, terbium doped.

Use/Import. (S) Luminescent powder. Import range: Confidential.

P 91-1176

Importer. Confidential.

Chemical. (G) Polyester urethane block polymer.

Use/Import. (G) Additive, open, nondispersive. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 4,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: none species (Rabbit).

P 91-1177

Manufacturer. PRatt & Lambert.

Chemical. (G) Amine-acrylate michael adduct.

Use/Production. (G) Component of industrial coating. Prod. range: Confidential.

P 91-1178

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid functional polymer of acrylates and methacrylate.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1179

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid functional polymer of styrene, acrylates and methacrylates.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1180

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid functional polymer of styrene, acrylates and methacrylates.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1181

Manufacturer. Confidential.

Chemical. (G) Amine salt of acids functional polymer of styrene, acrylates and methacrylates.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1182

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid functional polymer of styrene, acrylates and methacrylates.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1183

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid functional polymer of styrene, acrylates and methacrylates.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1184

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1185

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1186

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1187

Manufacturer. Confidential.

Chemical. (G) Amine salt of acid.

Use/Production. (G) Component of dispersively used coating. Prod. range: 70,000-140,000 kg/yr.

P 91-1188

Manufacturer. Bedoukian Research, Inc.

Chemical. (S) Bicyclo(3,3,1)hept-3-EN-2-OL, 4,6,6,-trimethykl-,(1*S*-(1*a*,2*b*,5*a*))-.

Use/Production. (S) Agricultural phenomone. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5.0 g/kg species (Rat). Skin irritation: slight species (Rabbit).

P 91-1189

Manufacturer. Rhone-Poulenc, Inc.

Chemical. (G) Acrylic copolymr.

Use/Production. (G) Intermediate use. Prod. range: Confidential.

P 91-1190

Importer. Hoechst Celanese CorpoRation.

Chemical. (G) Substituted dichlorobenzothiazole.

Use/Import. (S) High tempeRature exhaust dyeing. Import range: 1,000-6,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: modeRate species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea pig).

P 91-1191

Importer. Hoechst Celanese CorpoRation.

Chemical. (G) Substituted dicjlorobenzothiazole.

Use/Import. (S) High tempeRature exhaust dyeing. Import range: 1,000–6,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: modeRate species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea pig).

P 91-1192

Manufacturer. Hoechst Celanese CorpoRation.

Chemical. (G) Substituted dichlorobenzothiazole.

Use/Import. (S) High tempeRature exhaust dyeing. Import range: 1,000–6,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: modeRate species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea pig).

P 91-1193

Manufacturer. Henkel CorpoRation.

Chemical. (S) Pentaerythritol, ester with isononanoic acid.

Use/Production. (S) Lubricant basestock. Prod. range: 50,000–80,000 kg/yr.

P 91-1194

Manufacturer. Henkel CorpoRation.

Chemical. (S) Pentaerythritol, ester with isononanoic acid.

Use/Production. (S) Lubricant basestock. Prod. range: 50,000–80,000 kg/yr.

P 91-1195

Importer. Confidential.

Chemical. (G) Metal alkyl.

Use/Import. (G) Catalyst contained use. Import range: Confidential.

P 91-1196

Manufacturer. Confidential.

Chemical. (G) UnsatuRated polyester resin.

Use/Production. (G) Coating component. Prod. range: Confidential.

P 91-1197

Manufacturer. Confidential.

Chemical. (G) Epoxidized polyaromatic resin.

Use/Production. (G) Manufacture of molded articles. Prod. range: Confidential.

P 91-1198

Manufacturer. Confidential.

Chemical. (G) Epoxidized polyaromatic resin.

Use/Production. (G) Manufacture of molded articles. Prod. range: Confidential.

P 91-1199

Manufacturer. Donlar CorpoRation.

Chemical. (G) Polyanhydroamino acid.

Use/Production. (S) intermediate in formation of poly. Prod. range: 5,000,000–37,000,000 kg/yr.

P 91-1201

Manufacturer. Confidential.

Chemical. (G) Alkylhydroxylamine.

Use/Production. (G) Petroleum processing agent. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5.0 g/kg species (Rat). Acute dermal toxicity: LD50 > 2.0 g/kg species (Rabbit). Eye irritation: none species (Rabbit). Skin irritation: slight species (Rabbit).

P 91-1202

Manufacturer. Products Research and Chemical CorpoRation.

Chemical. (G) Mercaptan terminated polyether polymer.

Use/Production. (G) Intermediate for polymer production. Prod. range: 97,000–290,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5.0 g/kg species (Rat). Eye irritation: mild species (Rabbit). Skin irritation: slight species (Rabbit). Mutagenicity: negative species (Guinea pig).

P 91-1203

Manufacturer. Products Research and Chemical CorpoRation.

Chemical. (G) Aloxysilane terminated polyether polymer.

Use/Production. (G) Polymer for manufacture of sealants and adhesives. Prod. range: 100,000–300,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: none species (Rabbit). Mutagenicity: negative species (Guinea pig).

P 91-1204

Manufacturer. Products Research and Chemical CorpoRation.

Chemical. (G) Alkyoxysilane terminated polyether polymer.

Use/Production. (G) Polymer for manufacture of sealants and adhesives. Prod. range: 100,000–300,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: none species (Rabbit). Mutagenicity: negative species (Guinea pig).

Dated: July 16, 1991.

Douglas W, Sellers,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 91-17373 Filed 7-19-91; 8:45 am]

BILLING CODE 6560-50-F

[OPTS-59910; FRL 3937-1]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of November 11, 1984, (49 FR 46066) (40 CFR 723.250), EPA published a rule which granted a limited exemption from certain PMN requirements for certain types of polymers. Notices for such polymers are reviewed by EPA within 21 days of receipt. This notice announces receipt of 10 such PMN(s) and provides a summary of each.

DATES: Close of review periods:

Y 91-168, July 8, 1991.

Y 91-169, July 11, 1991.

Y 91-170, July 14, 1991.

Y 91-171, July 15, 1991.

Y 91-172, 91-173, 91-174, July 18, 1991.

Y 91-175, 91-176, 91-177, July 29, 1991.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, rm. E-545, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: The following notice contains information

extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the TSCA Public Docket Office, NE-G004 at the above address between 8 a.m. and noon and 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays.

Y 91-168

Manufacturer. Confidential.

Chemical. (G) 2,2,4-Trimethyl-1,3-propanediol; isophthalic acid; adipic acid tert-butyl acetoacetate.

Use/Production. (S) Polymer for enamel paint. Prod. range: 100,000-250,000 kg/yr.

Y 91-169

Manufacturer. S. C. Johnson & Son, Inc.

Chemical. (G) Aqueous acrylic polymer.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

Y 91-170

Manufacturer. Arizona Chemical Company.

Chemical. (G) Rosin polymer, glycol ester.

Use/Production. (S) Surfactant. Prod. range: Confidential.

Y 91-171

Manufacturer. Confidential.

Chemical. (G) Ethylene glycol, neopentyl, 1,6-hexanediol, aromatic diacids polymer.

Use/Production. (G) Resin for coatings. Prod. range: Confidential.

Y 91-172

Manufacturer. Confidential.

Chemical. (G) Aqueous acrylic polymer.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

Y 91-173

Manufacturer. Confidential.

Chemical. (G) Aqueous acrylic polymer.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

Y 91-174

Manufacturer. Confidential.

Chemical. (G) Aqueous acrylic polymer.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

Y 91-175

Manufacturer. Confidential.

Chemical. (G) Hydroxy functional acrylic polymer.

Use/Production. (S) Coatings. Prod. range: Confidential.

Y 91-176

Manufacturer. Confidential.

Chemical. (G) Hydroxy functional acrylic polymer.

Use/Production. (S) Coatings. Prod. range: Confidential.

Y 91-177

Manufacturer. Continental Polymers, Inc.

Chemical. (G) Poly(methyl methacrylate-co-imide).

Use/Production. (G) Heat modified acrylic. Prod. range: Confidential.

Dated: July 16, 1991.

Steven Newburg-Rinn,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 91-17372 Filed 7-19-91; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Submissions Required of 220 MHZ Nationwide Applicants

July 15, 1991.

This information is issued to clarify submission requirements under § 90.713 of the Commission's Rules for applicants for nationwide systems in the 220-222 MHz band.

Section 90.713 of the Rules, adopted in the Report and Order in PR Docket No. 90-552, sets entry requirements for nationwide 220 MHz systems and requires applicants to make specific submissions, including certifications, construction schedules, and financial qualifications. Section 90.713 becomes effective on July 29, 1991, 90 days after publication in the **Federal Register**. See 56 FR 19598 (April 29, 1991). The Report and Order stated that after approval of the new information collection requirements by the Office of Management and Budget, we would advise applicants when to make their submissions. No such submissions need to be filed at this time. We will apprise nationwide applicants of the procedures for filing § 90.713 submissions when we determine that it is appropriate to do so.

For further information about this matter, contact Rosalind Allen, Private Radio Bureau, Land Mobile and Microwave Division, Rules Branch at (202) 634-2443.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-17342 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

[Report No. 1852]

Petitions for Reconsideration and Clarification of Actions in Rule Making Proceedings

July 16, 1991.

Petitions for reconsideration have been filed in the Commission rule making proceedings listed in this Public Notice and pursuant to 47 CFR 1.429(e). The full text of these documents are available for viewing and copying in room 239, 1919 M Street, NW., Washington, DC, or may be purchased from the Commission's copy contractor Downtown Copy Center (202) 452-1422. Oppositions to these petitions must be filed on or before August 7, 1991. (See § 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Proposal to Reform the Commission's Comparative Hearing Process to Expedite the Resolution of Cases. (GEN Docket No. 90-264) Number of Petitions Received: 1.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-17337 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

[Report No. 1851]

Petitions for Reconsideration of Actions in Rule Making Proceedings

July 15, 1991.

Petitions for reconsideration have been filed in the Commission rule making proceedings listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of these documents are available for viewing and copying in room 239, 1919 M Street, NW., Washington, DC, or may be purchased from the Commission's copy contractor Downtown Copy Center (202) 452-1422. Oppositions to these petitions must be filed on or before August 7, 1991. See § 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of § 73.202(b), Table of Allotments, FM Broadcast Stations. (Stephenson, Michigan) (MM

Docket No. 89-500, RM-6970) Number of Petitions Received: 1.

Subject: Amendment of Part 15 of the Commission's Rules to Permit Cordless Telephone Operation on Offset Frequencies. (GEN Docket No. 89-626) Number of Petitions Received: 2.

Subject: Evaluation of the Syndication and Financial Interest Rules. (MM Docket No. 90-162) Number of Petitions Received: 7.

Subject: Establishment of Procedures to Provide a Preference to Applicants Proposing an Allocation for New Services. (GEN Docket No. 90-217) Number of Petitions Received: 5.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-17338 Filed 7-19-91; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS91-3]

Appraisal Subcommittee; Amendments to Chairperson's Delegation of Authority

AGENCY: Appraisal Subcommittee, Federal Financial Institutions Examination Council.

ACTION: Amendment to resolution delegating authority to the Chairperson.

SUMMARY: This notice announces that the Appraisal Subcommittee ("ASC") of the Federal Financial Institutions Examination Council ("FFIEC"), on July 10, 1991, amended its June 14, 1991 Resolution, which, among other things, delegated to the ASC Chairperson or his/her designee authority to reallocate resources within the ASC's annual budget.[1] The amendment clarifies the delegated authority by changing and adding new dollar parameters.

EFFECTIVE DATE: July 22, 1991.

FOR FURTHER INFORMATION CONTACT: Edwin W. Baker, Executive Director, or Marc L. Weinberg, General Counsel; Appraisal Subcommittee, Federal Financial Institutions Examination Council; 1776 G Street, NW.; suite 850B; Washington, DC 20006; (202) 357-0133.

SUPPLEMENTARY INFORMATION: Section 1102 (12 U.S.C. 3310) of title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA") [2] established the ASC and placed it within the FFIEC. Under title XI, the ASC must: (1) Monitor the Federal Financial Institutions Regulatory Agencies [3] and Resolution Trust Corporation's appraisal regulations; (2) monitor and review the practices, procedures, activities, and organizational structure of the Appraisal Foundation; (3) monitor State real estate appraiser certification and licensing programs; (4) maintain a national registry of State certified and licensed appraisers; and (5) review State compliance with title XI and take action against non-complying States.[4]

The amendment changes only paragraph two of the Resolution respecting the authority of the Chairperson or his/her designee to reallocate resources among object classes. More specifically, each reallocation exceeding $25,000 must be approved by the ASC, and each reallocation of $25,000 or less must be reported to the ASC monthly. In addition, an aggregate of no more than $50,000 in reallocations can be made without ASC approval between ASC meetings.

The ASC finds that the amendment should provide the ASC and its staff with an appropriate measure of financial flexibility to meet the needs of developing and administering the new, evolving title XI regulatory program. The ASC further finds that this agency action: (1) Is "a rule of agency organization, procedure, or practice" that does not require notice and public procedure under 5 U.S.C. 553(b); and (2) is not a "substantive rule" requiring at least 30 days between its publication in the **Federal Register** and effective date under 5 U.S.C. § 553(d).

For the reasons above, paragraph two of the June 14, 1991 Resolution is amended as follows:

Resolution

* * * * *

The Chairperson,

* * * * *

(2) Approves and/or delegates the approval of the distribution of budgetary resources in the form of a Budget Execution Plan and may reallocate resources among object classes so long as:

(a) * * *

(b) No single reallocation action exceeds $25,000 without the consent of the Subcommittee;

(c) An aggregate of not more than $50,000 in reallocations is allowed without Subcommittee approval between meetings of the Subcommittee; and

(d) Every reallocation of $25,000 or less shall be reported to the Subcommittee monthly.

Dated: July 17, 1991.

Fred D. Finke,

Chairman.

[FR Doc. 91-17376 Filed 7-19-91; 8:45 am]

BILLING CODE 6210-01-M

[1] 56 FR 28561 (June 21, 1991).

[2] Public Law No. 101-73, 103 Stat. 511 (1989); 12 U.S.C. 3310, 3331-3351.

[3] The Federal Financial Institution Regulatory Agencies are: the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation; the Office of the Comptroller of the Currency, the Office of Thrift Supervision, and the National Credit Union Administration, title XI, 1121(6); 12 U.S.C. 3350(6).

[4] See title XI, 1118, 12 U.S.C. 3347.

FEDERAL RESERVE SYSTEM

Agency Forms Under Review

July 15, 1991

Background

Notice is hereby given of the final approval of proposed information collection(s) by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.9 (OMB Regulations on Controlling Paperwork Burdens on the Public).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Office—Frederick J. Schroeder—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829).

OMB Desk Officer—Gary Waxman—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, room 3208, Washington, DC 20503 (202-395-7340).

Final Approval Under OMB Delegated Authority of the Extension With Revisions, of the Following Report

1. *Report Title:* Report of Transaction Accounts, Other Deposits and Vault Cash; Reports of Certain Eurocurrency Transactions; and Advance Reports of Deposits

Agency form number: FR 2900; FR 2950/51; and FR 2000/2001

OMB Docket Number: 7100-0087

Frequency: Weekly, Quarterly, Daily—dependent upon report

Reporters: Depository institutions

Annual reporting hours: 1,863,459

Report	Estimated No. of respondent	Estimated hours per response
FR 2900	9,198 (weekly)	1 to 12 (3.50 avg.)
	5,746 (quarterly	1 to 12 (3.50 avg.)
FR 2950/ 2951.	796 (weekly)	.2 to 5 (1.00 avg.)
	2 (quarterly	.2 to 5 (1.00 avg.)
FR 2000	186	.3 to 2.4 (.84 avg.)
FR 2001	540	.3 to 3 (.96 avg.)

Small businesses are affected.

General Description of Reports

This information collection is mandatory (12 U.S.C. 248 (a), 461, 603, 615, and 1305(b)(2) and is given confidential treatment (5 U.S.C. 552b(4).

This package of reports collects information on: Deposits and related items from depository institutions that have transaction accounts or nonpersonal time deposits and that are not fully exempt from reserve requirements (FR 2900); Eurocurrency transactions from depository institutions that obtain funds from foreign (non-U.S.) sources or that maintain foreign branches (FR 2950, FR 2951); and selected items on the FR 2900 in advance from samples of commercial banks on a daily basis (FR 2000) and on a weekly basis (FR 2001). The Federal Reserve System proposes to consolidate several items now reported on the FR 2900 as separate items, largely in response to the reduction to zero of the reserve requirement on nonpersonal time deposits that became effective in December 1990, but also because of developments in deposit markets that have reduced the value of certain items. The proposed revisions would reduce the number of data items collected on the FR 2900 from 21 to 14. Information provided by these reports is used for administering Regulation D—Reserve Requirements of Depository Institutions; or for constructing, analyzing, and controlling the monetary and reserves aggregates; or both.

Final Approval Under OMB Delegated Authority of the Extension Without Revision, of the Following Reports

1. *Report title:* Quarterly Report of Selected Deposits, Vault Cash and Reservable Liabilities; and Annual Report of Total Deposits and Reservable Liabilities.
Agency form number: FR 2910q; FR 2910a
OMB Docket number: 7100–0175
Frequency: Quarterly; Annually
Reporters: Depository Institutions
Annual reporting hours: 8,003

Report	Estimated No. of respondents	Estimated average hours per response
FR 2910q	612	2.00
FR 2910a	6,213	.50

Small businesses are affected.

General Description of Reports

This information collection is mandatory (12 U.S.C. 248(a) and 461) and is given confidential treatment (5 U.S.C. 552b(4)).

These reports collect information from depository institutions (other than U.S. branches and agencies of foreign banks and Edge and Agreement corporations) that are fully exempt from reserve equirements under the Garn-St Germain Depository Institutions Act of 1982. Information provided by these reports is used to construct and analyze the monetary aggregates and to ensure compliance with Regulation D—Reserve Requirements of Depository Institutions. No changes are proposed for these reports.

2. *Report title:* Allocation of Low Reserve Tranche and Reservable Liabilities Exemption
Agecny form number: FR 2930; FR 2930a
OMB Docket number: 7100–0088
Frequency: Annually, and on occasion
Reporters: Depository institutions
Annual reporting hours: 53
Estimated average hours per response: .25
Estimated number of respondents: 210
Small businesses are affected.

General Description of Reports

This information collection is mandatory (12 U.S.C. 248(a) and 461), and is given confidential treatment (5 U.S.C. 552b(4)).

This report provides information on the allocation of the low reserve tranche and reservable liabilities exemption for depository institutions having offices (or groups of offices) that submit separate FR 2900 deposits reports. The data collected by these reports are needed for the calculation of required reserves. No changes are proposed for these reports.

Board of Governors of the Federal Reserve System, July 15, 1991.

William W. Wiles,

Secretary of the Board.

[FR Doc. 91–17275 Filed 7–19–91; 8:45 am]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

[Announcement Number 147]

National Institute for Occupational Safety and Health; Drake Health Registry, Availability of Funds for Fiscal Year 1991

Introduction

The Centers for Disease Control (CDC), National Institute for Occupational Safety and Health (NIOSH), announces the availability of funds for Fiscal Year 1991 for a cooperative agreement with the Department of Health, Commonwealth of Pennsylvania, to provide assistance in maintaining a surveillance system and cohort registry for former employees of the Drake Chemical company and in developing and implementing an approach for future maintenance of the program by the private sector. The cooperative agreement will significantly strengthen the occupational public health infrastructure by integrating resources for occupational safety and health research and public health prevention programs at the state and local levels. The Public health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering Healthy People 2000 see the section Where to Obtain Additional Information.)

Authority

This program is authorized under section 20(a) of the Occupational Safety and Health Act of 1970 (42 U.S.C. 669), section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)), and section 104(d)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(d)(1)).

Eligible Applicants

Assistance will be provided only to the Pennsylvania Department of Health (PDOH). No other applications will be solicited or will be accepted.

PDOH has unique characteristics and capacities to meet the objectives. It is proposed a cooperative agreement be negotiated only with PDOH for the following reasons:

1. The PDOH has been responsible for the development and implementation of a registry and screening program for this cohort since 1986.

2. The PDOH and its subcontractor are the only organizations with all the names and addresses of cohort members and of the records of the exposure and screening history of the cohort. No one else can effectively perform the project without access to the cohort list and the medical records.

3. Since the goal of this program is to develop a plan for the transition of the maintenance of the registry to the private sector, only the PDOH can provide records and information to the various private organizations and health insurance carriers who might manage individual screenings.

Availability of Funds

Approximately $100,000 will be available in Fiscal Year 1991 to fund the PDOH. The award is expected to begin on or about September 30, 1991, for a 12-month budget period. The cooperative agreement is for a 3-year project period.

Background

The former Drake Chemical Company site located in Lock Haven, Clinton County, Pennsylvania, has been designated by the U.S. Environmental Protection Agency (EPA) as eligible for superfund intervention. The Drake Chemical Company, Inc., purchased the eight-acre Kilsdonk Chemical Company site in 1962 and continued the production of specialty intermediate chemicals for procedures of dyes, pharmaceuticals, cosmetics, textiles, plant additives, and pesticides. Chemicals used, manufactured and/or stored at the Drake site include the human carcinogens beta-naphthylamine, benzidine, and benzene as well as the herbicide fenac (trichlorophenylacetic acid), dichlorobenzene, arsenic, and pentachlorophenol.

Studies have described adverse health effects which are possibly associated with exposure to hazardous substances at the Drake site. "An Epidemiological Study of Occupational Bladder Cancer," published in 1963 by Dr. J. Lieben, concluded that bladder cancer appeared to affect a younger age group among this area's dye workers than among the local general population. A health hazard evaluation conducted by the National Institute for Occupational Safety and Health (NIOSH), CDC in 1981 at the Drake Chemical Facility documented reports of gingival bleeding, rashes, respiratory complaints, frequent irritative symptoms, and three current cases of bladder cancer as well as anecdotal accounts of two exposed workers having died of bladder cancer in the 1960s.

The Drake Chemical Company is no longer in business. The registry and screening program were established in 1986 to address the medical surveillance needs of the workers from this company. The purpose of the initial cooperative agreement, in 1986, was to identify all the workers from the plant, inform them of the risk of bladder cancer, and develop a registry that would allow for the ongoing follow-up and medical screening for bladder cancer. After five years of the program, it is believed that the program can be handled primarily in the private sector by individual private insurers and community social service or volunteer organizations.

Purpose

The purpose of this new cooperative agreement is to develop and implement a plan for the phased transfer of the registry and screening program to the private sector. The objectives are to find existing or new mechanisms to obtain ongoing medical monitoring of workers currently in the exposure registry. The approach will be to identify private insurers, community groups, and various community organizations and businesses that could be involved in this effort and to identify the issues involved in private sector screening of workers at high risk of disease. During the three-year award period, while a transfer plan is being developed, the continued maintenance of the registry and screening program will be supported.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A. below and CDC will be responsible for conducting activities under B. below:

A. Recipient Activities

1. The PDOH will continue the maintenance of the registry and screening program. It will ensure that the program design addresses the distinct characteristics and needs of the Drake cohort. It will devise approaches for a transition of programs from the public to the private sector. It will identify elements in maintaining such a registry that may be generalized for similar situations.

2. The PDOH will maintain an accounting system that keeps an accurate, complete, and current accounting of all financial transactions on site-specific basis. All supporting documentation will be retained, for possible use in cost recovery litigation with potentially responsible parties, for a minimum of 10 years after submission of a final Financial Status Report.

B. CDC/NIOSH Activities

CDC will assist PDOH to evaluate the impact of the Drake health Registry and Screening Program, and devise ways of obtaining private sector support for the Drake Health Registry.

Evaluation Criteria

The application will be reviewed based on the evidence submitted which specifically describes the applicant's ability to meet the following criteria:

1. Responsiveness to the objectives of the cooperative agreement including: (a) The applicant's understanding of the objectives of the proposed cooperative agreement, and (b) the relevance of the proposal to the objectives. (25%)

2. Feasibility of meeting the proposed goals of the cooperative agreement including the proposed schedule for initiating and accomplishing each of the activities of the cooperative agreement. (20%)

3. Strength of the program design which addresses the distinct characteristics and needs of the Drake cohort. (15%)

4. Strength of the proppsed program for developing approaches for transition of the registry and screening programs from the public to the private sector. (20%)

5. Training and experience of the proposed Program Director and staff including: (a) A Program Director who is a recognized scientist and technical expert, and (b) staff with training or experience sufficient enough to accomplish the proposed program. (20%)

6. The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of funds. (Not Scored)

Executive Order 12372

Applications are subject to the Intergovernmental Review of Federal Programs as Governed by Executive Order 12372. Executive Order 12372 sets up a system for state and local government review of proposed Federal assistance applications. Applicants (other than Federally-recognized Indian tribal governments) should contact their state Single Point of Contacts (SPOCs) as early as possible to alert them to the prospective applications and receive any necessary instructions on the state process.

For proposed projects serving more than one state, the applicant is advised to contact the SPOC of each affected state. A current list is included in the application kit. If SPOCs have any state

process recommendations on applications submitted to CDC, they should forward them to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, Mailstop E-14, 255 East Paces Ferry Road, NE., Atlanta, Georgia 30305 no later than 30 days after the deadline date for new and competing awards. The granting agency does not guarantee to "accommodate or explain" for state process recommendations it receives after that date.

Catalog of Federal Domestic Assistance Number (CFDA)

The Catalog of Federal Domestic Assistance Number (CFDA) for this program is 93.283.

Application Submission and Deadline

PDOH must submit an original and two copies of the application PHS Form 5161-1 to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, Mailstop E-14, 255 East Paces Ferry Road, NE., room 300, Atlanta, Georgia 30305, on or before August 1, 1991.

Where to Obtain Additional Information

If you are interested in obtaining additional information regarding this project, please reference announcement 147 and contact the following: Business Management Technical Assistance, Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, Mailstop E-14, 255 East Paces Ferry Road, NE., room 300, Atlanta, Georgia 30305, or by calling (404) 842-6630 or FTS 236-6630.

Programmatic Technical Assistance: Paul Schulte, Ph.D., NIOSH, Centers for Disease Control, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, or by calling (513) 841-4475 or FTS 684-4475.

A copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the INTRODUCTION may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone (202) 783-3238).

Dated: July 15, 1991.

Larry W. Sparks,

Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. 91-17326 Filed 7-19-91; 8:45 am]

BILLING CODE 4160-19-M

[Announcement Number 163]

A Cooperative Agreement to Conduct Operational and Applied Research Related to the Global Eradication of Poliomyelitis

Introduction

The Centers for Disease Control (CDC) announces the availability of funds in Fiscal Year 1991 for a cooperative agreement with the World Health Organization (WHO) to carry out operational and applied research in support of the WHO initiative for the global eradication of poliomyelitis by the year 2000.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

Authority

This program is authorized under the Public Health Service Act, sections 301 (42 U.S.C. 241) and 317k (42 U.S.C. 247b(k)), as amended.

Eligible Applicant

WHO alone has an existing program which meets the needs of this proposed cooperative agreement, i.e., a directive by the 41st World Health Assembly (May 1988) to assist member nations in carrying out an initiative to eradicate wild poliovirus transmission globally by the year 2000. In addition, WHO has: (1) Access to all national immunization programs and potential research sites through its six Regional Offices located in Washington, DC, Copenhagen, Denmark, Alexandria, Egypt, Brazzaville, The Congo, Dehli, India, and Manila, The Philippines, and, (2) formally convened expert committees to advise the Expanded Programme on Immunization (EPI), WHO, on the most important areas of operational and applied research in support of the polio eradication program. Assistance will only be provided to WHO, Geneva, Switzerland. No other applications are solicited or will be accepted.

Availability of Funds

Approximately $250,000 is available in Fiscal Year 1991 to fund one award. It is expected that the award will begin on or about September 1, 1991, for a 12-month budget period within a 3-year project period. Funding estimates may vary and are subject to change. Continuation awards within an approved project period will be made on the basis of satisfactory performance and the availability of funds.

Purpose

Widespread administration of trivalent oral poliovirus vaccine (OPV) has been associated with the virtual elimination of wild poliovirus infection in industrialized countries, as well as substantial reductions in the incidence of the disease in much of the developing world. However, the effectiveness of OPV in a number of tropical countries has been lower than expected, particularly in inducing neutralizing antibody against poliovirus types 1 and 3. In addition, outbreaks of poliomyelitis have occurred in areas with high levels of immunization coverage with three or more doses of OPV, including Taiwan (1982), Brazil (1986), The Gambia (1986), and Oman (1988). While there is some evidence to suggest that mass vaccination campaigns can interrupt transmission of wild polioviruses, the optimal age group and size of the geographic areas for which such campaigns should be targeted have not been established. In addition, factors which influence the emergence of such outbreaks in some countries but not in others remain largely unexplored. These and other gaps in current knowledge regarding the diagnosis and epidemiologic features of poliomyelitis and the optimal means of controlling and eliminating the disease must be addressed to facilitate achievement of the global eradication target.

Program Objectives

The objective of this cooperative agreement is to address existing and emerging impediments in achieving the goal of eradicating wild poliovirus infection by the year 2000 through a systematic program of applied and operational research. Such research is considered essential to refine control strategies as the eradication initiative matures, particularly strategies which are both feasible and cost-effective under a wide variety of circumstances.

Program Requirements

A. Recipient Activities

1. To collaborate in the development of a list of priorities for operational and applied research in support of the polio eradication initiative, in consultation with expert advisory committees (the EPI Research and Development Group and Global Advisory Group) and EPI Regional Advisors and program managers.

2. To collaborate in the development and/or solicitation of proposals to address these priorities.

3. To identify suitable study sites in which each proposal can be carried out.

4. To assist in the administration, monitoring, and analysis of each project.

5. To revise and/or expand the list of research priorities as dictated by the needs of the program.

B. CDC Activities

1. To collaborate in the development of protocols and/or review of solicited proposals.

2. To assist in the analysis and interpretation of data generated from each project.

3. To provide other technical assistance in support of each project as needed.

Evaluation Criteria

The application will be reviewed and evaluated by an ad hoc committee convened by CDC according to the following major considerations:

1. The extent to which short-term and long-term objectives are realistic, measurable, time-phased, and related to recipient activities (20 points).

2. The overall potential effectiveness of the applicants proposed activities and methods for meeting the stated objectives (30 points).

3. The adequacy of plans to evaluate progress in implementing methods and achieving objectives (30 points).

Consideration will be given for the extent to which the budget request is clearly justified and consistent with the intended use of the funds.

Other Requirements

Human Subjects—WHO must be responsible for assuring Human Subjects procedures are adhered to for any study conducted under this announcement.

Executive Order 12372 Review

The application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.185, Immunization Research, Demonstration, Public Information, and Education, Training, and Clinical Skills Improvement Projects.

Application Submission and Deadline

The original and two copies of the application (PHS Form 5161–1) must be submitted to Edwin L. Dixon, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., room 300, Atlanta, GA 30305, on or before August 1, 1991.

A. Deadline. The application shall be considered as meeting the deadline if it is either:

1. Received on or before the deadline date, or

2. Sent on or before the deadline date and received in time for submission to the independent review group. The applicant must request a legibly dated postmark or obtain a legibly dated receipt from a commercial carrier or postal service. Private metered postmarks shall not be accepted as proof of timely mailing.

B. Late Application: An application which does not meet the criteria in A.1 or A.2 above is considered a late application. A late application will not be considered and will be returned to the applicant.

Where to Obtain Additional Information

If you are interested in obtaining additional information regarding this cooperative agreement, please reference Announcement 163 and contact the following:

Business management technical assistance: Eddie L. Wilder, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., room 300, Atlanta, GA, 30305, telephone (404) 842–6640.

Programmatic technical assistance: Stephen Hadler, M.D., or Peter A. Patriarca, M.D., Division of Immunization, Center for Prevention Services, Centers for Disease Control, Atlanta GA 30333, (404) 639–1864.

A copy of Healthy People 2000 (Full Report; Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report; Stock No. 017–001–00473–1) referenced in the INTRODUCTION may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone 202–783–3238).

Dated: July 16, 1991.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 91–17325 Filed 7–19–91; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. N–91–3274; FR–3054–N–01]

Procedure for Reporting Prohibited Actions by FHA Mortgagees

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice and request for public comments.

SUMMARY: This notice is issued in compliance with the new section 539(a)(2) of the National Housing Act. That section requires the Secretary of HUD to establish a procedure under which any person may file a request that HUD determine whether a mortgagee is in compliance with statutory prohibitions against (1) minimum loan amounts for insured mortgages or (2) "tiered pricing" practices in connection with insured single family mortgages. Under the procedure HUD will inform the person requesting a determination of the disposition of his or her request and will publish in the **Federal Register** the disposition of any case referred to the Mortgagee Review Board.

FOR FURTHER INFORMATION CONTACT: William Heyman, Director, Office of Lender Activities and Land Sales Registration, 451 Seventh Street, SW., room 9146, Washington, DC, 20410, telephone: (202) 708–1824. The Telecommunications Device for the Deaf (TDD) number is (202) 708–4594. (These are not toll–free numbers).

SUPPLEMENTARY INFORMATION: Section 330(a) of the National Affordable Housing Act (Public Law 101–625) adds to section 203 of the National Housing Act (12 U.S.C. 1709) a new subsection (t). The new section 203(t) prohibits lenders from originating or holding FHA insured single family mortgages if it is the customary lending practice of the lender to provide for a variation in mortgage charges (i.e., interest rate, discount points, loan origination fee, and any other amount charged to a mortgagor with respect to an insured mortgage) of more than 2 percent in either a metropolitan statistical area or, in rural areas, within a county. The new section 203(t) further requires the Secretary to ensure that any variation in mortgage charges be based only on the actual variation in costs to the lender to make the loan.

All FHA section 203 insured single family mortgages of the same mortgage type (e.g., same level of risk, etc.) are subject to the 2 percent limitation. Although the new subsection is currently effective, the Department is developing a proposed rule to help interpret and implement the provision.

Section 535 of the National Housing Act (12 U.S.C. 1735f-13) prohibits a mortgagee or lender from requiring that the principal amount of an insured loan exceed a certain minimum amount before that mortgagee or lender will accept a loan application.

Section 223(a)(7)(B) of the National Housing Act (12 U.S.C. 1715m(a)(7) contains a prohibition on minimum principal amount similar to section 535 but relating specifically to the refinancing of insured mortgages.

Section 330(b) of the National Affordable Housing Act (Public Law 101-625) adds a new section 539(a) to the National Housing Act that requires, among other things, that the Secretary establish a procedure whereby any person may file a request for a determination on whether a mortgagee is in compliance with the new section 203(t), as well as sections 223(a)(7)(B) and 535. Section 539(a) further requires that the Secretary establish a procedure to inform each requestor of the disposition of the request for determination and to publish in the **Federal Register** the disposition of any request referred to the Mortgagee Review Board for action.

The address to be used when submitting a request for determination of compliance with section 103(t), 223(a)(7)(B) or 535 follows: Department of Housing and Urban Development, Office of Lender Activities and Land Sales Registration, 451 Seventh Street, SW., room 9146, Washington, DC 20410.

Each request must include the requestor's name and address and the name and address of the mortgagee/lender involved. In addition, a complete explanation of the circumstances and the mortgagee's practices, to the extent known, must be delineated. Any documented evidence that the requestor may have, including copies of advertisements, HUD-1 Settlement Statements, sales contracts, or other relevant documentation would greatly expedite the Department's review and the resultant determination.

This Notice is being issued in compliance with above-cited section 539(a)(2) of the National Housing Act. The Department will be issuing permanent regulations based upon this initial notice within the period required by the statute.

The information collection requirements contained in this Notice have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1980. Pending approval of this collection of information by OMB and the assignment of an OMB control number, no person making a request under this Notice will be subject to any penalty for failure to fully comply with the information collection requirements set forth in the Notice.

Dated: July 9, 1991.

Ronald A. Rosenfeld,

General Deputy Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 91-17352 Filed 7-19-91; 8:45 am]

BILLING CODE 4210-27-M

[Docket No. D-91-953; FR-3067-D-01]

Redelegation of Authority

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of redelegation of authority.

SUMMARY: This notice redelegates from the Assistant Secretary for Housing—Federal Housing Commissioner and the General Deputy Assistant Secretary for Housing to Regional Counsel, Chief Counsel, Chief Attorneys, Regional Directors of Housing, and Directors of Housing Management, or their designees, in HUD Regional and Field Offices in HUD Regions VI, VII, VIII, IX and X and to three named attorneys in the Office of General Counsel, HUD Central Office and one named attorney in the Office of Regional Counsel, Region III, the authority to perform a variety of functions in connection with foreclosures of properties in the name of Trustee Services Incorporated ("TSI") or Associates Service Corporation ("ASC") for, or on behalf of, HUD.

EFFECTIVE DATE: July 10, 1991.

FOR FURTHER INFORMATION CONTACT: Donald B. Alexander, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, SW., room 9258, Washington, DC 20410, (202) 708-3070. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under a delegation of authority published in the **Federal Register** at 54 FR 22033 on May 22, 1989, the Secretary of Housing and Urban Development delegated to the Assistant Secretary for Housing—Federal Housing Commissioner and the General Deputy Assistant Secretary for Housing "the power and authority of the Secretary of Housing and Urban Development with respect to all Housing programs and functions," including the authority with respect to Mortgagee Activities (including title I lenders) for Single Family programs to execute any "written instrument relating to real property or any interest therein heretofore or hereafter acquired by the Secretary pursuant to the National Housing Act", as well as "the authority to redelegate to employees of the Department."

On October 1, 1988, the Department entered into a contract with Trustee Services Incorporated ("TSI"), under which delinquent notes, and mortgages or deeds of trust securing the notes, acquired by the Secretary of Housing and Urban Development under title I of the National Housing Act, were assigned to TSI and its subsidiary, Associates Service Corporation ("ASC") for foreclosure. On October 18, 1990, HUD was notified that TSI and ASC were in the process of liquidation. As a result, TSI and ASC are no longer capable of carrying out their foreclosure responsibilities under the contract with the Department.

On November 29, 1990, TSI and ASC executed Special Powers of Attorney appointing the Department as their true and lawful attorney to enter into and execute any contracts, deeds, mortgages, deeds of trust, or any other document or monetary instruments whatsoever; to assign and transfer any instrument whatsoever; and to perform any other services whatsoever in connection with TSI or ASC performed for HUD in connection with foreclosures of properties for, or on behalf of, HUD.

Pursuant to the delegation of authority from the Secretary of Housing and Urban Development to the Assistant Secretary and the General Deputy Assistant Secretary, published in the **Federal Register** at 54 FR 22033 on May 22, 1989, the Assistant Secretary and the General Deputy Assistant Secretary are now redelegating (as set forth specifically below) the authority vested in the Department by virtue of the Special Powers of Attorney from TSI and ASC to certain HUD field office officials specified in this delegation and to four named HUD attorneys.

Accordingly, the Assistant Secretary for Housing—Federal Housing Commissioner and the General Deputy Assistant Secretary redelegate this authority as follows.

The Regional Counsel, Chief counsel, Chief Attorneys, Regional Directors of Housing, and Directors of Housing Management, or their designees, in HUD Regional and Field Offices in HUD

Regions VI, VII, VIII, IX and X and the following individuals: (1) Dolores L. Keegan, Attorney, Office of Regional Counsel, Region III; (2) Donald B. Alexander, Attorney, Office of General Counsel, HUD Central Office; (3) Robert S. Ernst, Attorney, Office of General Counsel, HUD Central Office; and (4) Jeffery H. Swartzbaugh, Attorney, Office of General Counsel, HUD Central Office, are authorized to exercise the following powers and authorities with respect to properties covered by the Special Powers of Attorney dated November 29, 1990 wherein Trustee Services Incorporated ("TSI") and Associates Service Corporation ("ASC") appointed HUD as their true and lawful attorney:

1. The authority to enter into, sign, endorse, seal, execute, acknowledge and deliver any contracts, deeds, mortgages, deeds of trust, or any other document or monetary instruments whatsoever;

2. The authority to assign and transfer any note, mortgage, deed of trust, or any other instrument whatsoever; and

3. The authority to perform any other services whatsoever in connection with TSI or ASC performed for the Department of Housing and Urban Development in connection with foreclosures of properties for, or on behalf of, HUD.

Authority: Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: July 10, 1991.

Ronald A. Rosenfeld,

General Deputy Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 91-17351 Filed 7-19-91; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-010-01-4713]

Boise District Advisory Council; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting, Idaho.

SUMMARY: The Boise District Advisory Council will conduct a field tour of the Owyhee Backcountry Byway on August 21, 1991 and will hold a Council meeting on August 22, 1991. The meeting is open to the public and a comment period will be held at 1 p.m.

DATES: The meeting will begin at 8:30 a.m. on Thursday, August 22 at the Lion's Hall in Jordan Valley, Oregon.

FOR FURTHER INFORMATION CONTACT: Barry Rose, Boise District, BLM (208) 384-3393.

Dated: July 9, 1991.

Barry C. Cushing,

Acting District Manager.

[FR Doc. 91-17287 Filed 7-19-91; 8:45 am]

BILLING CODE 4310-66-M

Phoenix District Advisory Council; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting of the Phoenix District Advisory Council.

DATES: September 5-6, 1991.

SUMMARY: The Phoenix District Advisory Council of the Bureau of Land Management meets September 5-6, 1991 at the Phoenix District's Kingman Resource Area Office, 2475 Beverly Avenue, Kingman, Arizona 86401 to discuss and make recommendations on various public land issues. The Council will meet at 10:30 a.m. on Thursday, September 5, at the Kingman Resource Area Office and from there depart on a full-day field trip to the Hualapai Mountains. The Council will hold its regular meeting at the Kingman Resource Area Office at 9 a.m. on September 6, 1991.

The Council has been established by and will be managed according to the Federal Advisory Committee Act of 1972, the Federal Land Policy and Management Act of 1976, and the Public Rangeland Improvement Act of 1978.

The agenda for the meeting includes:

—Kingman Resource Area Resource Management Plan

—Field Trip to the Hualapai Mountains

—Business from the Floor

—Public Comments and Statements

—Future Meetings and Agenda Topics

SUPPLEMENTARY INFORMATION: This is a public meeting and the Bureau of Land Management welcomes the presentation of oral statements or the submission of written statements that address the issues on the meeting agenda or related matters. The Bureau of Land Management welcomes the participation of any interested member of the public in the all-day tour scheduled for Thursday, September 5 and business meeting on September 6. Members of the public wishing to join the tour should be at the Kingman Resource Area Office at 10:30 a.m. on September 5 and must provide their own transportation and lunches.

Dated: July 11, 1991.

Henri R. Bisson,

District Manager.

[FR Doc. 91-17288 Filed 7-19-91; 8:45 am]

BILLING CODE 4310-20-M

[ID-942-01-4730-12]

Idaho: Filing of Plats of Survey; Idaho

The plat of survey of the following described land was officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9:00 a.m., July 11, 1991.

The plat representing the dependent resurvey of portions of the subdivision lines and subdivision of section 14, T. 1 N., R. 1 W., Boise Meridian, Idaho, Group No. 807, was accepted July 10, 1991.

This survey was executed to meet certain administrative needs of the Bureau of Land Management.

All inquiries concerning the survey of the above-described land must be sent to the Chief, Branch of Cadastral Survey, Idaho State Office, Bureau of Land Management, 3380 Americana Terrace, Boise, Idaho, 83706.

Dated: July 11, 1991.

Duane E. Olsen,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 91-17289 Filed 7-18-91; 8:45 am]

BILLING CODE 4310-66-M

Office of Surface Mining Reclamation and Enforcement

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1029-0029), Washington, DC 20503, telephone 202-395-7340.

Title: Surface Coal Mining and Reclamation Operations; Coal Exploration Operations; Termination of Jurisdiction 30 CFR part 700

OMB Number: 1029–0029
Abstract: Information collected in § 700.11(d) is used by The Office of Surface Mining Reclamation and Enforcement (OSM) and States to establish a point where a mine site is no longer a surface coal mining and reclamation operation and regulatory jurisdiction ends. Information collected under § 700.12(b) is used by OSM to consider the need, costs, and benefits, of a proposed regulatory change in order to grant or deny a petition that has been submitted. Information collected in § 700.13 identifies the person and nature of a citizens suite, so that the Regulatory Authority can respond appropriately.
Bureau Form Number: None
Frequency: On occasion
Description of Respondents: Surface Coal Mining Operators, Members of the Public
Estimated Completion Time: 31 hours
Annual Responses: 10
Annual Burden Hours: 306
Bureau Clearance Officer: Richard L. Wolfe (202) 343–5143
Dated: June 6, 1991.

John P. Mosesso,

Chief, Division of Technical Services.

[FR Doc. 91–17290 Filed 7–19–91; 8:45 am]
BILLING CODE 4310–05–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 31911]

Chicago and North Western Transportation Co.—Trackage Rights Exemption—The Commuter Rail Division of the Regional Transportation Authority

The Commuter Rail Division of The Regional Transportation Authority has agreed to grant overhead trackage rights to Chicago and North Western Transportation Company in Chicago, IL, over that portion of its line that extends from Consolidated Rail Corporation's track connection with Norfolk and Western Railway Company at approximately 73rd Street, a distance of approximately 4.05 miles. The trackage rights were to become effective on or after July 16, 1991.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Myles L. Tobin, Chicago and North Western Transportation Company, One North Western Center, Chicago, IL 60606.

As a condition to the use of this exemption, any employees affected by the trackage rights will be protected pursuant to Norfolk and Western Ry. Co.—Trackage Rights— BN, 354 I.C.C. 605 (1978), as modified in Mendocino Coast Ry., Inc.—Lease and Operate, 360 I.C.C. 653 (1980).

Dated: July 15, 1991.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 91–17374 7–19–91; 8:45 am]
BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Fleet/Norstar Financial Group, Inc.

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b) through (h), that a proposed Final Judgment, Stipulation and Competitive Impact Statement have been filed with the United States District Court for the District of Maine in *United States* v. *Fleet/Norstar Financial Group, Inc.*, Civil Action No. 91–0221–P.

The Complaint in this case alleges that the proposed acquisition of New Maine National Bank by Fleet/Norstar Financial Group, Inc. would violate section 7 of the Clayton Act, as amended, 15 U.S.C. 18, by lessening competition for the provision of business banking services in Bangor, Presque Isle-Caribou, and Pittsfield, Maine.

The proposed Final Judgment directs the defendant to sell designated bank branches in each geographic market and is subject to approval by the Court after the expiration of the statutory 60-day public comment period and compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h).

Public comment is invited within the statutory 60-day comment period. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Constance K. Robinson, Chief, Communications and Finance Section, Antitrust Division, room 8104, 555 Fourth Street, NW., Washington, DC 20001, (202–514–5621).

Joseph H. Widmar,

Director of Operations, Antitrust Division.

Filed 7/5/91, Civil Docket No. 91–0221–P, Judge Carter.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. 16), and without further notice to any party or other proceedings, provided that plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on defendants and by filing that notice with the Court.

2. The parties shall abide by and comply with the provisions of the Final Judgment pending entry of the Final Judgment.

3. In the event plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation will be of no effect whatever, and the making of this Stipulation shall be without prejudice to any party in this or any other proceeding.

Dated: July 5, 1991.

Portland, Maine July 5, 1991.

For the plaintiff:

Richard S. Cohen, United States Attorney, District of Maine.

By:

Frederick C. Emery, Jr., Assistant U.S. Attorney, 100 Middle Street, East Tower, Sixth Floor, Portland, Maine, Telephone: (207) 780–3257.

Of Counsel for the Plaintiff:

Charles A. James, Acting Assistant Attorney General.
Contance K. Robinson, Chief, Communications and Finance Section.
Donald J. Russell, Assistant Chief, Communications and Finance Section, U.S. Department of Justice, Antitrust Division, Washington, DC 20001.
Patricia A. Shapiro, Jennifer L. Otto, Laury Bobbish, Attorneys, U.S. Department of Justice, Antitrust Division, Judiciary Center Building, 555 4th Street, NW., Washington, DC 20001, (202) 514–5796.

Counsel for the Defendant:

Fleet/Norstar Financial Group, Inc.
William C. Mutterperl, 50 Kennedy Plaza, Providence, RI 02903, (401) 278–5880.
Michael A. Greenspan, Thompson & Mitchell, 700 14th Street, NW., Washington DC 20005, (202) 508–1005.
Robert S. Frank. Andrew M. Horton, c/o Verrill & Dana, One Portland Square, P.O. Box 586, Portland, Maine 04112, (207) 774–4000.

FINAL JUDGMENT

Whereas, Plaintiff, United States of America, having filed its Complaint herein on July 5, 1991, and plaintiff and defendant, by their respective attorneys, having consented to the entry of this Final Judgment without trial or

adjudication of any issue of fact or law herein and without this Final Judgment constituting any evidence against or an admission by any party with respect to any such issue;

And Whereas, defendant has agreed to be bound by the provisions of this Final Judgment pending its approval by the Court;

And Whereas, prompt and certain divestiture of bank branches is the essence of this agreement, and defendant has represented to plaintiff that the defendant believes the divestitures required herein can and will be made and that defendant will later raise no claims of hardship or difficulty as grounds for asking the Court to modify any of the divestiture provisions contained herein;

Now, Therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon consent of the parties hereto, it is hereby

Ordered, adjudged and decreed as follows:

I. Jurisdiction

This Court has jurisdiction over the subject matter of this action and over each of the parties hereto. The Complaint states a claim upon which relief may be granted against defendant under section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. "Agreement" means the Agreement for the purchase of certain of the assets and assumption of certain of the liabilities by Fleet from the Federal Deposit Insurance Corporation for New Maine National Bank.

B. "Bangor Savings Bank" means Bangor Savings Bank, its successors and assigns, its parents, subsidiaries, affiliates, directors, officers, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it.

C. "Business banking services" means banking services offered to business customers which include at least:

1. "Transaction account deposits," *i.e.,* money deposited with a depository institution either at an agreed upon interest rate or at no interest, withdrawable in practice upon demand and upon which third party drafts may be drawn by the depositor, including checking accounts and NOW accounts; and

2. "Commercial loans," *i.e.,* secured or unsecured loans to businesses, excluding commercial mortgages. Business banking services may also include additional services such as cash and coin, lockbox, cash management, and business expertise and advice offered to business customers. Business banking services excludes services offered only to individual consumers.

D. "Branch assets" means personal property; cash on hand; the branch loan portfolio; all safe deposit boxes at the branches, exclusive of contents; all prepaid expenses, including security deposits of the branches, determined in accordance with generally accepted accounting principles, as of the closing date; all rights of defendant to all contracts relating to the branch; all records and original documents in defendant's possession pertaining to the leasehold, the personal property, the branch loans, the mortgage loans and the nondeposit liabilities; any leasehold; any real estate, buildings, structures, drive-in teller facilities, ATMs, fixtures and improvements thereon which are owned and used by defendant as premises for the branches; and any other assets required for the branch to compete effectively in offering business banking services. Branch assets does not include those assets that at the request of the purchaser are excluded from a branch sale, such as classified loans, signs, and computer equipment not useful to a purchaser.

E. "Branch deposits" means liabilities allocated to a branch that constitute the unpaid balance of money or its equivalent received or held by the branch in the usual course of business and for which the branch has given or is obligated to give credit, either conditionally or unconditionally, to a commercial, checking, savings, time, or thrift account, or which is evidenced by its certificate of deposit, or a check or draft drawn against a deposit account and certified by the branch.

F. "Casco Northern Bank" means Casco Northern Bank, N.A., its successors and assigns, its parents, subsidiaries, affiliates, directors, officers, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it.

G. "Commercial mortgages" means loans secured by real estate as evidenced by mortgages or other liens on business and industrial properties.

H. "Defendant" or "Fleet" means Fleet/Norstar.

I. "Fleet/Norstar" means the defendant Fleet/Norstar Financial Group, Inc., its successors and assigns, its subsidiaries, affiliates, directors, officers, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it. Fleet/Norstar shall include Fleet Bank of Maine and NMNB and any of its assets after such time, if any, as Fleet acquires NMNB.

J. "Fleet Presque Isle" means the Fleet office located at 373 Main Street, Presque Isle, Maine in the Presque Isle-Caribou market.

K. "Fleet Stillwater" means the Fleet office located at the Bangor Mall, 663 Stillwater Avenue, Bangor, Maine in the Bangor market.

L. "Key Bank" means Key Bank, its successors and assigns, its subsidiaries, affiliates, directors, officers, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it.

M. "MSB" means Maine Savings Bank, its successors and assigns, its subsidiaries, affiliates, directors, officers, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it.

N. "NMNB" means the New Maine National Bank, an FDIC bridge bank, its successors and assigns, its subsidiaries, affiliates, directors, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it pursuant to the Agreement.

O. "NMNB Merchants Plaza" means the NMNB office located at One Merchants Plaza, Bangor, Maine in the Bangor market. NMNB Merchants Plaza does not include the trust officers or fiduciary documents or related trust matcrials currently at that location.

P. "NMNB Orono" means the NMNB office located at 69 Main Street, Orono, Maine in the Bangor market.

Q. "NMNB Pittsfield" means the NMNB office located at 27 Main Street, Pittsfield, Maine in the Pittsfield market.

R. "NMNB Union" means the NMNB office located at 599 Union Street, Bangor, Maine in the Bangor market.

S. "Peoples Heritage Savings Bank" means Peoples Heritage Savings Bank, its successors and assigns, its subsidiaries, affiliates, directors, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it.

T. "Relevant geographic market. means any or all of the following geographic areas:

(a) The "Bangor market" means the Bangor MSA plus the Penobscot County townships of Alton, Amherst, Argyle, Bradford, Bradley, Carmel, Charlestown, Clifton, Corinth/East Corinth, Dixmont, Etna, Greenbush, Greenfield, Hudson,

LaGrange, Levant, Milford, Newburgh, and Stetson; the Hancock County townships of Bucksport, Castine, Dedham, Orland, Otis and Verons; the Waldo County townships of Frankfort, Prospect and Stockton Springs; and unorganized townships T1N.D. and T32M.D. in the State of Maine;

(b) The "Pittsfield market" means the Waldo County township of Burnham; the Somerset County townships of Cambridge, Detroit, Harmony, Hartland, Palmyra, Pittsfield, Ripley and St. Albans; the Penobscot County townships of Corinna, Dexter, Exeter, Garland, Newport and Plymouth; and the Piscataquis County township of Wellington in the State of Maine; and

(c) The "Presque Isle Caribou market" means the Aroostook County townships of Ashland, Blaine, Bridgewater, Caribou, Castle Hill, Caswell, Chapman, Connor, Cox, Patent, Easton, Fort Fairfield, Garfield, Limestone/Loring AFB, Mapleton, Mars Hill, Masardis, Nashville, New Sweden, Oxbow, Perham, Portage Lake, Presque Isle, Squapan, Stockholm, Wade, Washburn, Westfield, Westmanland and Woodland, plus unorganized townships T14R-5, T13R-5, T9R-5, T9R-4, T9R-3, T11R-4, T10R-6, T10R-3, TDR-2 and TEP1 in the State of Maine.

U. "Skowhegan Savings Bank" means Skowhegan Savings Bank, its successors and assigns, its subsidiaries, affiliates, directors, officers, managers, agents, and employees, any other persons under its direct or indirect control, and any other person acting for or on behalf of it.

III. Applicability

A. The provisions of this Final Judgment shall apply to the defendant, to its successors and assigns, to its subsidiaries, affiliates, directors, officers, managers, agents, and employees, and to all other persons in active concert or participation with any of them who shall have received actual notice of this Final Judgment by personal service or otherwise.

B. Defendant shall require, as a condition of the sale or other disposition of all or substantially all of its assets or stock, that the acquiring party agree to be bound by the provisions of this Final Judgment.

C. Nothing herein shall suggest that any portion of this Final Judgment is or has been created for the benefit of any third party, and nothing herein shall be construed to provide any rights to any third party.

IV. Divestiture of Branches

A. Defendant is hereby ordered and directed to divest to a qualified purchaser(s), within six (6) months of the date of filing of this Final Judgment, all of their direct and indirect ownership and control in the branch assets and deposits identified below. The purchaser(s) shall be independent of defendant; shall be federally insured financial institution(s) that offer business customers, at a minimum, transaction account deposits and commercial loans; shall deliver promptly to plaintiff following the execution of a binding contract(s), an affidavit from an authorized officer stating a present intention that the branch(es) purchased will offer business banking services in the geographic area currently served by the branch(es); and shall be subject to approval by plaintiff. The obligation to divest shall be satisfied if, within six (6) months of the date of filing of this Final Judgment, defendant enters into a binding contract(s) with qualified purchasers for the sale of the branch assets and deposits at each location listed below to a purchaser(s) according to terms approved by plaintiff that are contingent upon compliance with the terms of this Final Judgment and that specify a prompt and reasonable closing date no later than ten (10) business days after compliance with all federal or state bank regulatory requirements and if the sale is completed pursuant to the contract(s). In the event that any proposed divestiture is denied approval by the Board of Governors of the Federal Reserve System or any other federal or state bank regulatory agency, the time period specified herein in which defendant must complete the sale of the section IV.B. branch locations will expire on the six (6) month anniversary date of the filing of this Final Judgment, unless plaintiff under section IV.C grants additional time.

B. Defendant is hereby ordered and directed to divest:

1. The Fleet Presque Isle branch assets and deposits in the Presque Isle Caribou market. The purchaser cannot be Key Bank, Peoples Heritage Savings Bank or Casco Northern Bank.

2. The NMNB Pittsfield branch assets and deposits in the Pittsfield market. The purchaser cannot be Key Bank, Peoples Heritage Savings Bank or Skowhegan" Savings Bank.

3. The Fleet Stillwater branch assets and deposits in the Bangor market. The purchaser cannot be Bangor Savings Bank or Peoples Heritage Savings Bank.

4. The NMNB Merchants Plaza branch assets and deposits in the Bangor market. The purchaser cannot be Bangor Savings Bank or Peoples Heritage Savings Bank.

5. The NMNB Orono branch assets and deposits in the Bangor market. The purchaser cannot be Bangor Savings Bank or Peoples Heritage Savings Bank.

6. The NMNB Union branch assets and deposits in the Bangor market. The purchaser cannot be Bangor Savings Bank or Peoples Heritage Savings Bank.

C. If defendant has not accomplished the required divestiture(s), within six (6) months of the filing date of this Final Judgment, plaintiff may, in its sole discretion, extend this time period, separately for each section IV.B branch location, for an additional period of time, if defendant requests such an extension and demonstrates to plaintiff's satisfaction for each such branch location that it is then engaged in negotiations with a prospective purchaser(s) that are likely to result in the required divestiture(s) but that the divestiture(s) cannot be completed by the six (6) month anniversary date of the filing of this Final Judgment.

D. Defendant agrees to take all reasonable steps to accomplish quickly said divestitures. In carrying out its obligation to divest the branch assets and deposits at each location identified in section IV.B. of this Final Judgment, defendant may divest these branch assets alone, or may divest along with these branch assets any other assets of Fleet/Norstar or NMNB.

E. In accomplishing the divestitures ordered by this Final Judgment, the defendant, promptly after filing of this Final Judgment, shall make known in the Wall Street Journal, the American Banker, and in the State of Maine, by usual and customary means, the availability of the section IV.B. branch locations, for sale as ongoing branches that offer business banking services. The defendant shall notify any person making an inquiry regarding the possible purchase of any or all of the section IV.B. branch locations that the sale is being made pursuant to this Final Judgment and that this Final Judgment requires approval of this Court. The defendant shall provide any such person with a copy of this Final Judgment. The defendant shall also offer to furnish to all bona fide prospective purchasers of any or all of the section IV.B. branch locations, subject to customary confidentiality assurances, all pertinent information regarding each section IV.B. branch location. Defendant shall provide such information to the plaintiff as soon as possible, but no later than two (2) business days after it furnishes such information to any other person. Defendant shall permit prospective purchasers of any or all of the section IV.B. branch locations to have access to personnel at each section IV.B. branch location and to make such inspection of

physical facilities and any and all financial, operational, or other documents and information as may be relevant to the sale of each section IV.B. branch location. Defendant shall not be required to permit prospective purchasers to have access to any documents or information relevant to defendant's banking business, except to the extent it relates to the section IV.B. branch locations, operations and business. Defendant shall not object to any application for new bank charters sought to facilitate any divestiture(s).

F. Divestiture required by section IV.B. of this Final Judgment shall be accomplished in such a way as to satisfy plaintiff, in its sole discretion that the purchaser is qualified in the following two respects: (1) The purchaser intends to use the section IV.B. branch assets and deposits to compete in the provision of business banking services in the geographic area currently served by the branch, and (2) the purchaser has the managerial, operational, and financial capability to compete effectively in the provision of such business banking services.

G. Following accomplishment of divestitures, defendant shall not acquire or attempt to acquire any branch assets divested pursuant to section IV.B. of this Final Judgment without first receiving prior approval from the plaintiff during the duration of this Final Judgment.

H. Except to the extent otherwise approved by plaintiff, any branch assets divested pursuant to this Final Judgment shall be divested free and clear of (1) all mortgages, encumbrances and liens to Fleet/Norstar (2) any contractual commitments or obligations to Fleet/Norstar existing as of the date of divestiture, unless plaintiff is satisfied that the purchaser of a divested branch location wishes to voluntarily assume the future performance of any such existing contracts, and plaintiff consents thereto.

V. Appointment of Trustee

A. If defendant has not accomplished the divestiture(s) required by section IV.B. of this Final Judgment by the five (5) month anniversary date of the filing of this Final Judgment, defendant shall notify plaintiff in writing of that fact. Within ten (10) days of that date, or twenty (20) days prior to the expiration of any extension granted pursuant to section IV.C., whichever is later, plaintiff shall provide defendant with written notice of the names and qualifications of not more than two (2) nominees for the position of trustee for the required divestitures. Defendant shall notify plaintiff within ten (10) days thereafter whether either or both of such nominees are acceptable. If either or both of such nominees are acceptable to defendant, plaintiff shall notify the Court of the person upon whom the parties have agreed and the Court shall appoint that person as the trustee. If neither of such nominees is acceptable to defendant, it shall furnish to plaintiff, within ten (10) days after plaintiff provides the names of its nominees, written notice of the names and qualifications of not more than two (2) nominees for the position of trustee for the required divestitures. If either or both of such nominees are acceptable to plaintiff, plaintiff shall notify the Court of the person upon whom the parties have agreed and the Court shall appoint that person as the trustee. If neither of such nominees is acceptable to plaintiff, it shall furnish the Court with the names and qualifications of its proposed nominees and the names and qualifications of the nominees proposed by defendant. The Court may hear the parties as to the qualifications of the nominees and shall appoint one of the nominees as the trustee.

B. If defendant has not accomplished all of the divestiture(s) required by section IV.B. of this Final Judgment at the expiration of the time period specified in sections IV.A. or IV.C. of this Final Judgment, as applicable, the appointment by the Court of the trustee shall become effective. The trustee shall then take steps to effect divestiture of the not yet divested section IV.B. branch locations according to the terms of this Final Judgment; provided, however, that the appointment of the trustee shall not become effective if, prior to expiration of the applicable time period, defendant has notified plaintiff pursuant to section VI. of this Final Judgment of a proposed divestiture(s) of section IV.B. branch locations and plaintiff has not filed a written notice that it objects to said proposed divestiture(s).

C. After the trustee's appointment has become effective, only the trustee shall have the right to sell any section IV.B. branch location as to which it has been designated to effect divestiture. The trustee shall have the power and authority to accomplish divestitures to a purchaser(s) acceptable to the plaintiff at such price and on such terms as are then obtainable upon a reasonable effort by the trustee, subject to the provisions of section VI. of this Final Judgment, and shall have such other powers as this Court shall deem appropriate. Defendant shall not object to a sale of the section IV.B. branch locations by the trustee on any grounds other than the trustee's malfeasance. Any such objection by defendant must be conveyed in writing to plaintiff and the trustee within fifteen (15) days after the trustee has notified defendant of the proposed sale in accordance with section VI. of this Final Judgment.

D. The trustee shall serve at the cost and expense of defendant, shall receive compensation based upon a fee arrangement which includes an incentive based upon the price of the divestitures and the speed with which they are accomplished, and shall serve on such other terms and conditions as the Court may prescribe; provided, however, that the trustee shall receive no compensation, nor incur any costs or expenses, prior to the effective date of his or her appointment. The trustee shall account for all costs and expenses incurred in connection with its assignment in this matter. After approval by the Court of the trustee's accounting, including fees and reasonable expenses for his or her services, all remaining monies shall be paid to defendant and the trust shall then be terminated.

E. Defendant shall take no action to interfere with or impede the trustee's accomplishment of the divestiture(s) and shall, if requested by the trustee, use its best efforts to assist the trustee in accomplishing the required divestiture(s). The trustee shall have full and complete access to the personnel, books, records, and facilities of the section IV.B. branch locations which the trustee is designated to divest, and defendant shall develop such financial or other information relevant to the section IV.B branch locations being divested as the trustee may request.

F. After its appointment becomes effective, the trustee shall file monthly reports with the parties and the Court setting forth the trustee's efforts to accomplish divestiture(s) as contemplated under this Final Judgment; provided, however, that to the extent such reports contain information that the trustee deems confidential, such reports shall not be filed in the public docket of the Court. Such reports shall include the name, address, and telephone number of each person who, during the preceding thirty (30) days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted, or made an inquiry about acquiring, any ownership interest in the section IV.B. branch locations, and shall describe in detail each contact with any such person during that period. The trustee shall maintain full records of all efforts made to divest the section IV.B branch locations and shall provide additional information to plaintiff upon its request.

G. Within six (6) months after its appointment has become effective, if the trustee has not accomplished the divestiture(s) required by section IV.B of this Final Judgment, the trustee shall promptly file with the Court a report setting forth (1) the trustee's efforts to accomplish the required divestitures, (2) the reasons, in the trustee's judgment, why any required divestitures have not been accomplished, and (3) the trustee's recommendations; provided, however, that to the extent the report contains information that the trustee deems confidential, the report shall not be filed in the public docket of the Court. The trustee shall at the same time furnish the report to the parties, who shall each have the right to be heard and to make additional recommendations consistent with the purpose of the trust. The Court shall thereafter enter such orders as it shall deem appropriate in order to carry out the purpose of the trust and the term of the trustee's appointment.

VI. Notification

Immediately following execution of a binding contract(s), contingent upon compliance with the terms of this Final Judgment, to effect any proposed divestitures pursuant to section IV. of this Final Judgment, defendant or the trustee, whichever is then responsible for effecting the divestitures, shall notify plaintiff of the proposed divestitures. If the trustee is responsible, it shall similarly notify defendant. The notice shall set forth the details of the proposed transactions and list the name, address, and telephone number of each person not previously identified who offered to, or expressed an interest in or desire to, acquire any ownership interest in the section IV.B. branch locations, together with full details of same. Within fifteen (15) days of receipt by plaintiff of such notice, plaintiff may request additional information concerning the proposed divestiture(s) and the proposed purchaser(s). Defendant and/or the trustee shall furnish any additional information requested within twenty (20) days of receipt of the request, unless the parties shall otherwise agree. Within thirty (30) days after receipt of the notice or within twenty (20) days after plaintiff has been provided the additional information requested (including any additional information requested of persons other than the defendant or the trustee), whichever is later, plaintiff shall provide written notice to defendant and to the trustee, if there is one, stating whether or not it objects to the proposed divestiture(s). If plaintiff provides written notice to defendant and/or the trustee that it does not object, then the divestiture(s) may be consummated, subject only to defendant's limited right to object to the sale under the proviso in section V.C. Upon objection by plaintiff, a divestiture proposed under section IV. shall not be consummated. Upon objection by plaintiff, or by defendant under the proviso in section V.C., a divestiture proposed under section V. shall not be consummated unless approved by the Court.

VII. Affidavits

Within five (5) business days of filing of this Final Judgment and every thirty (30) days thereafter until the divestitures have been completed or authority to effect divestitures passes to the trustee pursuant to section V. of this Final Judgment, defendant shall deliver to plaintiff an affidavit as to the fact and manner of compliance with section IV. of this Final Judgment. Each such affidavit shall include the name, address, and telephone number of each person who, at any time after the period covered by the last such report, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any ownership interest in the section IV.B. branch locations, and shall describe in detail each contact with any such person during that period. Defendant shall maintain full records of all efforts made to divest the section IV.B. branch locations.

VIII. Financing

Defendant shall not finance all or any part of any purchase made pursuant to sections IV. or V. of this Final Judgment without plaintiff's prior consent.

IX. Preservation of Assets

Until the divestiture of the section IV.B. branch locations required by this Final Judgment have been accomplished:

A. The defendant shall take all steps necessary to assure that the section IV.B. branch locations will be maintained as economically viable, ongoing branches that offer business banking services. The defendant shall use all reasonable efforts to maintain and increase sales of business banking services at the section IV.B. branch locations, and continue with any current plans for development of business banking services at those locations.

B. The defendant shall not sell, lease, assign, transfer or otherwise dispose of, or pledge as collateral for loans, any branch assets required to be divested pursuant to section IV.B., except that any component of such branch assets as is replaced in the ordinary course of business with a newly purchased component may be sold or otherwise disposed of, provided the newly purchased component is so identified as a replacement component for one to be divested.

C. The defendant shall provide capital and provide and maintain sufficient working capital to maintain the section IV.B. branch locations, including funds for commercial lending, as viable, ongoing branches that offer business banking services consistent with the requirements of section IX.A.

D. Defendant shall preserve the branch assets and deposits required to be divested pursuant to sections IV. and V., except those replaced with newly acquired branch assets and deposits in the ordinary course of business, in a state of repair equal to their state of repair as of the date of this Final Judgment, ordinary wear and tear excepted. Defendant shall preserve the documents, books and records of the section IV.B. branch locations until the date of divestiture.

E. Except in the ordinary course of business, or as is otherwise consistent with the requirements of section X., the defendant shall refrain from terminating or altering one or more current employment, salary, or benefit agreements (except that defendant may substitute its benefit agreement provided that the employees of the section IV. branch locations receive benefits comparable to those of other Fleet Bank of Maine employees) for one or more managerial or commercial loan personnel of the section IV.B. branch locations, and shall refrain from transferring any employee so employed without the prior written approval of plaintiff.

F. Defendant shall refrain from taking any action that would jeopardize the sale of the section IV.B. branch locations.

X. Employment Offers

A. Defendant is hereby enjoined and restrained until two (2) years following the date of divestiture, from employment of, or making offers of employment to, any person who currently is a commercial loan manager, officer or representative, the preponderance of whose duties relate to the successful operation of the section IV.B. branch locations. This provision, however, does not apply to any employee who is terminated by the purchaser of a divested branch. Defendant shall encourage and facilitate employment by the purchaser of such employees, and shall remove any impediments that exist which may deter such employees from accepting employment with the

purchaser of any section IV.B. branch locations, including, but not limited to, the payment of all bonuses accrued up to the closing date of sale of each section IV.B. branch location to which such employees would otherwise have been entitled had they remained in the employment of defendant until December 31, 1991.

XI. Visitorial Clause

For the purpose of determining or securing compliance with this Final Judgment, and subject to any legally recognized privilege, from time to time:

A. Duly authorized representatives of the Department of Justice shall, upon written request of the Attorney General or of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to the defendant made to its principal office, be permitted:

1. Access during office hours of the defendant to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of the defendant, who may have counsel present, relating to any matters contained in this Final Judgment; and

2. Subject to the reasonable convenience of the defendant and without restraint or interference from it, to interview officers, employees and agents of the defendant, who may have counsel present, regarding any such matters.

B. Upon the written request of the Attorney General or of the Assistant Attorney General in charge of the Antitrust Division made to the defendant's principal office, the defendant shall submit such written reports, under oath if requested, with respect to any of the matters contained in this Final Judgment as may be requested.

No information or documents obtained by the means provided in this section XI. shall be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

C. If at the time information or documents are furnished by the defendant to plaintiff, the defendant represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and the defendant marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then ten (10) days notice shall be given by plaintiff to the defendant prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which the defendant is not a party.

XII. Expiration of Judgment

This Final Judgment will expire on the tenth anniversary of its date of entry or, with respect to any particular provision, on any earlier date specified.

XIII. Retention of Jurisdiction

Jurisdiction is retained by this Court for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for such further orders or directions as may be necessary or appropriate for the construction or carrying out of this Final Judgment, for the modification of any of the provisions hereof, for the enforcement of compliance herewith, and for the punishment of any violations hereof.

XIV. Statement of Public Interest

Entry of this Final Judgment is in the public interest.

United States District Judge.

Competitive Impact Statement

The United States, pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act ("APPA"), 15 U.S.C. 16(b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On July 5, 1991, the United States filed a civil antitrust complaint under section 15 of the Clayton Act, as amended, 15 U.S.C. 25, alleging that the proposed acquisition of New Maine National Bank ("NMNB"), one of the three bridge banks established by the Federal Deposit Insurance Corporation ("FDIC"), by Fleet/Norstar Financial Group, Inc. and its affiliate, Fleet Bank of Maine (referred to collectively as "Fleet"), would violate section 7 of the Clayton Act, as amended, 15 U.S.C. 18.

The complaint alleges that the effect of the acquisition may be substantially to lessen competition in the provision of business banking services in the Bangor, Pittsfield, and Presque Isle-Caribou geographic markets. Business banking services offered to business customers, include either collectively or individually, services such as checking accounts, commercial loans, or other services such as cash and coin, lockbox, cash management, and business expertise and advice. Both Fleet and NMNB compete directly in offering a variety of business banking services to business customers in each of the geographic markets. The proposed acquisition would result in substantial increases in concentration in markets that are already highly concentrated and for which regulatory and other market factors make it unlikely that effective entry will maintain competition in the relevant markets.

The complaint alleges that the proposed acquisition would, in particular, hurt the many small to medium-sized business customers purchasing business banking services in the Bangor, Pittsfield, and Presque Isle-Caribou markets. The complaint seeks, among other relief, to enjoin the proposed transaction and thereby to prevent its anticompetitive effects.

On July 5, 1991, the United States and Fleet filed a Stipulation by which they consented to the entry of a proposed Final Judgment. Under the proposed Final Judgment, as explained more fully below, defendant would be required to sell designated commercial banking branches [1] in each geographic market. The United States and the defendant have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the government withdraws its consent. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, and enforce the proposed Final Judgment and to punish violations of the Judgment.

II. Events Giving Rise to the Alleged Violation

On January 6, 1991, the FDIC was appointed as receiver of Bank of New England and reorganized it and its affiliates into three bridge banks in Connecticut, Massachusetts, and Maine. NMNB, one of the three bridge banks, formerly operated in the State of Maine as Maine National Bank. After establishing the bridge banks, the FDIC solicited bids for the purchase of these banks pursuant to its congressional authority to arrange assisted transactions. [2]

[1] The proposed Final Judgment requires divestiture of six commercial bank branches.

[2] 12 U.S.C. 1823(c). An "assisted transaction" under 12 U.S.C. 1823(c) can involve several different forms of assistance from the FDIC. The type of assistance rendered in this transaction included the FDIC's restoring Bank of New England and its

Continued

Under the statutory provisions applicable to FDIC assisted transactions, Congress mandated that such transactions be subject to antitrust review, both by the bank regulatory agencies involved and by the Department of Justice ("Department"). [3] Furthermore, Congress expressly provided that the Department can challenge assisted transactions that would violate section 7 of the Clayton Act. [4]

On April 22, 1991, the FDIC selected Fleet as the winning bidder. By the terms of Fleet's winning bid, Fleet would purchase certain assets and liabilities of the three bridge banks for $125 million, with $25 million being paid in cash and the remainder in preferred stock.

Fleet is the largest commercial bank operating in the State of Maine as measured by total deposits. Fleet controls total deposits of approximately $2.9 billion, which represent approximately 22 percent of total deposits from commercial banks and thrift institutions in the state. Fleet operates approximately 110 branch offices located throughout the State of Maine.

NMNB is the fifth largest commercial bank operating in the State of Maine, as measured by total deposits. NMNB controlled total deposits of approximately $959,712,000, which represent approximately 7 percent of total deposits from commercial banks and thrift institutions in the state. NMNB operates approximately 44 branches throughout the State of Maine.

On April 23, 1991, the Board of Governors of the Federal Reserve Board ("Board") approved an interim management agreement between Fleet and the FDIC for Fleet's management of the bridge banks. Pursuant to the interim management agreement, Fleet would provide management, operational and support services necessary to supervise and manage the bridge bank operations. This agreement will terminate upon consummation of the acquisition.

On May 14, 1991, Fleet submitted its formal applications to the Board for consummation of the acquisition. At the request of the FDIC, the application was treated as an emergency transaction for expedited review. On July 1, 1991, the Board approved Fleet's application for consummation of the acquisition.[5]

Under the Bank Merger Act, as amended, 12 U.S.C. 1828,[6] the United States had five days from the date of the Federal Reserve Board's decision to prevent the proposed acquisition by filing a complaint with the Court.

The United States filed its complaint because the proposed acquisition would likely reduce competition in the provision of business banking services in certain relevant geographic markets in Maine. The likelihood of competitive harm appears greatest for small to medium sized business customers because the proposed acquisition would eliminate one of only a few financial institutions serving these customers and would likely result in higher prices for business banking services.

Investigation by the United States shows that Fleet and NMNB compete in the provision of a wide range of banking services, including services to individual consumers and services to businesses in Maine. Many other financial institutions compete with Fleet and NMNB in the provision of consumer banking services. Only commercial banks and state chartered savings banks, however, are competitors for business customers in Maine. These are the only firms that provide business banking services, as defined in the complaint. Fleet and NMNB are two of the largest of these few firms. Fleet and NMNB each offer a variety of business banking services, and compete directly with one another ih the relevant geographic markets of: Bangor, Pittsfield, and Presque Isle-Caribou. A significant number of business customers purchase both transaction accounts and commercial loans as well as other business banking services from Fleet and NMNB.[7]

Few other financial institutions currently offer or appear likely to start offering within a reasonably short period of time business banking services in the relevant markets. Savings and loan associations are limited by law in the extent to which they make commercial loans; moreover, their ability to begin offering these services to businesses is substantially affected by capital requirements and their own capital positions. Under the Financial Institutions Reform, Recovery, and Enforcement Act of 1989,[8] new, more significant capital requirements and other restrictions were placed upon the lending activities of savings and loan associations. Moreover, savings and loan associations in the relevant markets do not currently provide business banking services. The United States, investigation revealed that the above factors coupled with other economic factors concerning the cost, scale and expertise involved in offering business banking services, make it unlikely that savings and loan associations will be likely entrants into the provision of such services.

The investigation also revealed that credit unions in Maine are generally not current or potential competitors in business banking services due to a combination of legal and economic restraints. Credit unions offer services to individual consumers, but are not permitted to offer business banking services such as those provided to the business customers served by commercial banks and state chartered savings banks. Credit unions clearly do not offer the full range of business banking services provided by commercial banks and state chartered savings banks; for these reasons credit unions were excluded as suppliers of business banking services.

Loan production offices ("LPOs") do not offer transaction accounts and, under current regulation, are prohibited from doing so. Moreover, the LPOs in the State of Maine do not currently provide com ercial loans to small and medium sized businesses. Based on available evidence, even with a significant, nontransitory price increase for commercial loans to small and medium-sized businesses, LPOs are unlikely profitably to enter and make such loans.

Non-depository institutions may provide one or even a few of the services provided by commercial banks and certain thrift institutions. For example, investment or brokerage houses offer products that are offered by

affiliates to normal operations and supervising those operations until a purchaser was selected through FDIC bidding procedures.

[3] See 12 U.S.C. 1823(f)(7) and 12 U.S.C. 1828(6) and (7)(a).

[4] See 12 U.S.C. 1828(6) and (7)(a).

[5] *Fleet/Norstar Financial Group, Inc.*, Federal Reserve System Order, July 1, 1991.

[6] Sections 1828(c) (6) and (7)(A), 12 U.S.C. 1828 (6) and (7)(a), provide in pertinent part that:

The responsible agency shall immediately notify the Attorney General of any approval by it pursuant to this subsection of a proposed merger transaction * * *. [T]he transaction may not be consummated before the fifth calendar day after the date of approval by the agency.

Any action brought under the antitrust laws arising out of a merger transaction shall be commenced prior to the earliest time under paragraph (6) at which a merger transaction approved under paragraph (5) might be consummated. The commencement of such, an action shall stay the effectiveness of the agency s approval unless the court shall otherwise specifically order. In any such action, the court shall review de novo the issues presented.

[7] Commercial loans include all loans to business customers not fully secured by real estate. Additional business banking services offered to business customers include but are not limited to cash and coin, lockbbx, cash management, and business expertise and advice.

[8] 12 U.S.C. 14647(t).

commercial banks or thrift institutions. Non depository institutions, however, do not provide certain important business banking services, such as transaction accounts for business customers, which are offered by commercial banks and some thrift institutions. Thus, they are not included as suppliers of business banking services.

In the Bangor market, five other financial institutions (Key Bank, Casco Northern Bank, United Bank, Bangor Savings Bank and Peoples Heritage Savings Bank) offer business banking services. In the Pittsfield market, three other financial institutions (Key Bank, Peoples Heritage Savings Bank and Skowhegan Savings Bank) offer business banking services; and in the Presque Isle-Caribou market, five other financial institutions (Casco Northern Bank, Key Bank, First Citizens Bank, Peoples Heritage Savings Bank and Machias Savings Bank) offer business banking services.

Numerous small and medium sized businesses operate in the State of Maine. Such businesses generally must obtain business banking services from banks which have offices in Maine, and many such businesses are economically able to obtain business banking services only from the banks located in the geographic markets where the business is situated. Business customers often purchase a number of different banking services from the bank with which they do business. For example, a business customer might use the bank for a checking account, credit for the purchase of inventory, payroll services, night deposit, and cash and coin.

The United States concluded that, for business banking services in Maine, the relevant geographic markets were those defined by the Federal Reserve Bank of Boston. Based on a variety of measures, the United States' investigation indicates that only a few firms provide business banking services, and a few of them have very large market shares; the others have much smaller market shares. In Bangor, Fleet is the leading firm by a significant margin, and in Pittsfield and Presque Isle-Caribou, Fleet and NMNB are in the category of the largest firms. This market structure is significant, because it means that combining the two firms will significantly increase concentration. Concentration is important because it indicates the likelihood that a group of firms could exercise market power (*i.e.*, raise prices or reduce output).

Under the Justice Department's Merger Guidelines,[9] when the Herfindahl Hirschman Index ("HHI"),[10] a measure of market concentration, is over 1800, additional concentration resulting from a merger is a matter of significant concern. Where the HHI would increase by more than 50 points, the Department is likely to challenge the merger unless the Department concludes, on the basis of other relevant factors, that the merger is not likely substantially to lessen competition.

In this regard, the United States factored into its decision to challenge the proposed acquisition and in evaluating the proposed settlement, the financial viability of NMNB. The United States carefully calculated and reviewed data relating to "runoff" (loss of deposits) resulting from the erosion of public confidence in and the FDIC's subsequent takeover of NMNB. The United States concluded, even after factoring in the loss of these deposits, that concentration levels in the three relevant geographic markets were not sufficiently reduced to mitigate competitive concerns resulting from the proposed acquisition. Moreover, the United States concluded that it was unlikely that entry of new competitors into these markets, or rapid expansion of the smallest firms currently in the markets would occur so as to prevent any anticompetitive effects.

In the Bangor market, the HHI, calculated on the basis of total deposits [11] of firms offering business banking services, would increase (as a result of seven firms going to six) by 510 to 3271 if the proposed acquisition occurred. In the Pittsfield market, the HHI would increase (as a result of five firms going to four) by approximately 556 to 2605. In the Presque Isle-Caribou market, the HHI would increase (as a result of seven firms going to six) by approximately 213 to 2218. These measures indicate highly concentrated markets that would be further concentrated as a result of the proposed acquisition.

Finally, the United States considered and rejected defendant's assertion regarding a successful "failing company defense." [12] Defendant argued that because the FDIC selected it as the winning bidder of the bridge banks, it was the only available purchaser despite the fact that an award to another bidder would have created no competitive concerns. Acceptance of this argument, however, would lead to the conclusion that the failing company defense is available in every FDIC-assisted transaction. Such an argument would preclude consideration by the FDIC, the Board, and the Department of the likely competitive effects of any such transaction or its effects on the convenience and needs of the community. Congress, however, clearly and explicitly mandated a consideration of those effects by the FDIC, the Board, and the Department.

For all the above reasons, the United States found that each of these markets is highly concentrated; that each would become substantially more concentrated as a result of the proposed acquisition; and that entry and expansion were unlikely to offset the anticompetitive effects.

III. Explanation of the Proposed Final Judgment

The risk to competition posed by this acquisition would be substantially reduced by the structural relief provided in the proposed Final Judgment in each of the relevant markets through divestiture of commercial bank branches. In addition, this structural relief substantially preserves the efficiencies that are anticipated to accrue from the acquisition.

Fleet is required, by section IV. of the proposed Final Judgment, within six months of the filing date of the proposed

[9] Department of Justice Merger Guidelines, 2 Trade Reg. Rep. (CCH) ¶ 13,102 at 20,529–30.

[10] The HHI is a measure of market concentration calculated by squaring the market share of each firm in the market and then summing the resulting numbers. For example, for a market supplied by four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 ($30^2+30^2+20^2+20^2=900+900+400+400=2600$). The HHI takes into account the relative sizes and distribution of firms in a market. It approaches zero when a market is supplied by a large number of firms of relatively equal size and reaches its maximum of 10,000 when a market is supplied by a single firm. The HHI increases both as the number of firms in the market decreases and as the disparities in size among these firms increases.

[11] There is a relationship between the ability to accept deposits and the granting of credit and the provision of other business banking services. The deposits accepted by a financial institution are an important source of the loans made by it and a principal source of funds to support other services.

[12] The failing company defense, which has been recognized since *International Shoe Co.* v. *Federal Trade Comm'n.*, 280 U.S. 291, 299–303 (1930), provides a defense for mergers that are otherwise anticompetitive that involve a failing or failed firm. Three elements are necessary for the defense:

(1) The allegedly failing firm probably would be unable to meet its financial obligations in the near future; (2) it probably would not be able to reorganize successfully * * * *; and (3) it has made unsuccessful good faith efforts to elicit reasonable alternative acquisition offers of an acquisition of the failing firm that would both keep the firm in the market and pose a less severe danger to competition than the proposed merger.

1984 *Merger Guidelines*, ¶5.1. The burden of establishing these elements, including the burden of showing the unavailability of a less anticompetitive alternative purchaser, rests on the merging parties. *United States* v. *General Dynamic Corp.*, 415 U.S. 486, 507 (1974); *Citizen Publishing Co.* v. *United States*, 394 U.S. 131, 138–39 (1969). In the United States, view, Fleet has not met that burden.

Final Judgment to divest the following commercial bank branches:

1. In the Bangor market, the NMNB Merchant Plaza, NMNB Union Street, NMNB Orono, and the Fleet Stillwater branch assets and deposits; and
2. In the Pittsfield market, the NMNB Pittsfield branch assets and deposits; and
3. In the Presque Isle-Caribou market, the Fleet Presque Isle branch assets and deposits.

To ensure that the divestitures are accomplished in such a way as to maintain competition, the proposed Final Judgment prohibits the sale of the branches to certain very large firms who already have a significant competitive presence in the geographic markets. The proposed Final Judgment prohibits the sale of any of the above branches to Peoples Heritage Savings Bank. In addition, Fleet cannot sell the Bangor branches to Bangor Savings Bank. Fleet cannot sell the Pittsfield branch to Key Bank or Showhegan Savings Bank. Fleet cannot sell the Presque Isle branch to Key Bank or Casco Northern Bank. The divestitures will bring about the entry of a new provider or make larger an existing, small provider of business banking services in each of these markets, thereby, ensuring that competition is not substantially lessened by the acquisition.

All purchasers must demonstrate to the satisfaction of the United States that they have a good faith intention to operate the divested branches as banking branches that offer business banking services. The proposed Final Judgment also requires that Fleet preserve the assets of the divested banking branches until purchased by a buyer. If Fleet fails to sell the branches within six months of the filing date of the proposed Final Judgment, Fleet shall file with the court and notify plaintiff within thirty days of the date the purchase contracts were required to be entered into by Fleet. The United States can then proceed under the terms of section V of the proposed Final Judgment to appoint a trustee to accomplish the branch divestitures.

The United States and Fleet have stipulated that the proposed Final Judgment may be entered by the Court at any time after compliance with the APPA. The proposed Final Judgment constitutes no admission by any party as to any issue of fact or law. Under the provisions of section 2(e) of the APPA, entry of the proposed Final Judgment is conditioned upon a determination by the Court that the proposed Final Judgment is in the public interest.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorney fees.[13] Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust actions under the Clayton Act. Under the provisions of section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no *prima facie* effect in any private lawsuit that may be brought against the defendant.

V. Procedures Available for Modification of the Proposed Final Judgment

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**. The United States will evaluate the comments, determine whether it should withdraw its consent, and respond to the comments. The comments and response(s) of the United States will be filed with the Court and published in the **Federal Register**.

Written comments should be submitted to Constance K. Robinson, Chief, Communications and Finance Section, Antitrust Division, U.S. Department of Justice, 555 Fourth Street, NW., room 8104, Washington, DC 20001.

The proposed Final Judgment provides that the Court retains jurisdiction over this action and any party may apply to the Court for any order necessary or appropriate for its modification, interpretation or enforcement.

VI. Alternatives to the Proposed Final Judgment

The United States considered the following alternatives regarding divestiture of bank branches. In the Bangor market, the United States considered requiring the defendant to divest the NMNB branch in Brewer; the United States also considered requiring divestiture of the Maine Savings Bank branch in Stillwater in lieu of the Fleet Stillwater branch. After evaluating the combined divestiture proposal for Bangor, the United States concluded that divestiture of the Fleet Stillwater branch and the NMNB branch on Union Street would resolve the United States' competitive concerns in the Bangor market.

As a final alternative to the proposed Final Judgment, the United States considered litigation for seeking an injunction to block Fleet's acquisition of NMNB. The United States rejected that alternative because the sale of the commercial bank branches will establish viable independent competitors to Fleet in all the relevant markets and likely will prevent the proposed acquisition from having significant anticompetitive effects in those markets.

VII. Standard of Review Under the Tunney Act for Proposed Final Judgment

The Antitrust Procedures and Penalties Act ("APPA"), 15 U.S.C. 16 (1974), requires that proposed consent judgments in antitrust cases brought by the United States are subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed final judgment "is in the public interest". In making that determination, the court *may* consider—

(1) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, and any other considerations bearing upon the adequacy of such judgment;

(2) The impact of entry of such judgment upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e). (emphasis added). The courts have recognized that the term, "public interest", "take(s) meaning from the purposes of the regulatory legislation."[14] Since the purpose of the antitrust laws is to "preserv(e) free and unfettered competition as the rule of trade,"[15] the focus of the "the public

[13] The Bank Merger Act, 12 U.S.C. 1828, however, prevents the filing of an antitrust suit (other than a suit under § 2 of the Sherman Act) later than five days after the July 1, 1991, Board order.

[14] *NAACP* v. *FPC*, 425 U.S. 662, 669 (1976).

[15] *Northern Pacific Railway Co.* v. *United States*, 356 U.S. 1, 4 (1958). See also *National Society of Professional Engineers* v. *United States*, 435 U.S. 679, 692 (1978).

interest" inquiry under the Tunney Act is whether the proposed final judgment would serve the public interest in free and unfettered competition.[16] In conducting this inquiry, "(t)he Court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process."[17] Rather,

(a)bsent a showing of corrupt failure of the government to discharge its duty, the Court, in making the public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.[18]

It is also unnecessary for the district court to "engage in an unrestricted evaluation of what relief would best serve the public." [19] Precedent requires that

the balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is "*within the reaches of the public interest.*" (citation omitted) More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree. (emphasis added).[20]

A proposed consent decree is an agreement between the parties which is reached after exhaustive negotiations and discussions. Parties do not hastily and thoughtlessly stipulate to a decree because, in doing so, they

waive their right to litigate the issues involved in the case and thus save themselves the time, expense, and inevitable risk of litigation. Naturally, the agreement reached normally embodies a compromise; in exchange for the saving of cost and the elimination of risk, the parties each give up something they might have won had they proceeded with the litigation.[21]

The proposed consent decree, therefore, should not be reviewed under a standard of whether it is certain to eliminate every anticompetitive effect of a merger or whether it mandates certainty of free competition in the future. Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. "[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.' (citations omitted)." [22]

VIII.—Determinative Documents

No documents were determinative in the formulation of the proposed Final Judgment. Consequently, the United States has not attached any such documents to the proposed Final Judgment.

Dated: July 10, 1991.

Respectfully submitted,
Constance K. Robinson,
Chief, Communications & Finance Section.
Donald J. Russell,
Assistant Chief, Communications & Finance Section.
United States Department of Justice, Antitrust Division.
Richard S. Cohen,
United States Attorney, District of Maine.
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David Collins,
Assistant United States Attorney, District of Maine.

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[16] *Accord United States* v. *American Cyanamid Co.*, 719 F.2d 558, 565 (2d Cir. 1983), *cert. denied*, 465 U.S. 1101 (1984); *United States* v. *Waste Management, Inc.*, 1985-2 Trade Cas. (CCH) ¶ 66,651 at 63,046 (D.D.C. 1985).

[17] 119 Cong. Rec. 24598 (1973). See *United States* v. *Gillette Co.*, 406 F. Supp. 713, 715 (D. Mass. 1975). A "public interest" determination can be made properly on the basis of the Competitive Impact Statement and Responses to Comments filed pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. See H.R. Rep. 93-1463, 93rd Cong. 2d Sess. 8-9, *reprinted in* (1974) U.S. Code Cong. & Ad. News 6535, 6538.

[18] *United States* v. *Mid-America Dairyman, Inc.*, 1977-1 Trade Cas. (CCH) ¶ 61,508 at: 71,980 (W.D. Mo. 1977).

[19] *United States* v. *BNS Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) *quoting United States* v. *Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir.), *cert. denied*, 454 U.S. 1083 (1981).

[20] *United States* v. *Bechtel, supra; United States* v. *BNS, Inc., supra*, 858 F.2d at 463; *United States* v. *National Broadcasting Co.*, 449 F. Supp. 1127, 1143 (C.D. Cal. 1978); *United States* v. *Gillette Co., supra*, 406 F. Supp. at 716. See also *United States* v. *American Cyanamid Co., supra.*

[21] *United States* v. *Armour & Co.*, 402 U.S. 673, 681 (1971).

[22] *United States* v. *American Tel. and Tel Co.*, 552 F. Supp. 131, 150 (D.D.C.), *aff'd*, 460 U.S. 1001 (1982) *quoting United States* v. *Gillette Co., supra*, 406 F. Supp. at 716; *United States* v. *Alcan Aluminum, Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky 1985).

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D-5700]

Proposed Class Exemption Relating to Certain Employee Benefit Plan Foreign Exchange Transactions; Correction

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Correction.

SUMMARY: In 56 FR published at page 11757 on Wednesday, March 20, 1991, make the following corrections:

1. On page 11763, in the first column, in section I(a), in the second line, delete "June 18, 1991" and insert therein "ninety days after the date of publication of the final exemption in the **Federal Register**".

2. On page 11763, in the first column, in Section I(b), in the first line, delete "June 18, 1991" and insert "ninety days after the date of publication of the final exemption".

Signed at Washington, DC, this 16th day of July, 1991.

Ivan L. Strasfeld,
Director of Exemption Determinations, Pension, and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 91-17365 Filed 7-19-91; 8:45 am]
BILLING CODE 4510-29-M

[Application No. D-8489, et al.]

Proposed Exemptions; Hudson Enterprises Profit Sharing Plan, et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice. Comments and request for a hearing should state: (1) the name, address, and telephone

number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, room N-5649, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, room N-5507, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Departent.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Hudson Enterprises Profit Sharing Plan (the Plan), Located in Newport Beach, California

[Application No. D-8489]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed loan of $450,000 from the Plan to the Orange Grove Shopping Center (the Center), a disqualified person with respect to the Plan, provided the terms this transaction are at least as favorable to the Plan as those the Plan could obtain in a similar transaction with an unrelated party.[1]

Summary of Facts and Representations

1. The Plan is a profit sharing plan covering only David Klein, the sole owner and the sole employee of the Plan sponsor. As of August 1990, the fair market value of the Plan's assets approximated $1.8 million. David Klein makes investment decisions for the Plan. The Plan sponsor owns a 90% interest in the Center, which is a partnership; the remaining 10% interest is owned by Robert and Sharon Berkelo, who are not related to the Plan or to David Klein.

2. The Center's partners are currently obligated under a note secured by deed of trust dated December 15, 1980 to repay by December 15, 1995 a loan of $820,591.75 (the Current Loan) from John Vanian and Daniel Vanian, who are not parties in interest with respect to the Plan and are not otherwise related to the Plan sponsor. As of November 16, 1990, the unpaid balance due under the Current Loan was $732,091. From December 15, 1990 until the Current Loan matures on December 15, 1995, the monthly payment due under the Current Loan is $2,000 per month with interest ($2,260). At maturity (December 15, 1995), the balance due under the Current Loan will approximate $612,000, which will be due and payable on that date. The Current Loan does not prohibit or limit the Center from making additional secured or perfected loans.

3. The Plan proposes to lend $450,000 to the Center at an interest rate of 13% annually to be paid monthly by the Center. The proposed installment note documenting the loan agreement provides that the loan will be repaid over a 60-month period and in monthly payments of principal and interest, each payment equal to at least $12,375. The note permits the Center to pay more than the sum due at any time. To secure the proposed loan, the Center will issue a second trust deed giving the Plan a perfected security interest in the Center's property, which interest will be recorded with the necessary local county officials. Insurance against casualty and liability loss claims will be maintained on the property for the Plan's benefit. The note also provides that amounts payable upon default will be payable immediately and that the Plan shall receive from the Center a loan origination fee of $25,000 upon the signing of the note. The proposed loan proceeds will be used for further improvements to the Center's property and, if necessary, to liquidate the balance of the Current Loan when it becomes due in 1995.

4. By letter dated October 16, 1989, David M. Esterkes, sales consultant with Coldwell Banker Commercial Real Estate Services, stated his belief that the value of the Center's property was between $3,600,000 and $4,020,000. Further, Ronald L. Buss (Mr. Buss), MAI, CRE, and Thomas W. Baaden (Mr. Baaden), associate, of Buss-Shelger Associates, an independent real estate valuation firm, have personally inspected and appraised the Center's property, which is located at 445-497 E. Orange Grove Blvd., at Los Robles Avenue, in the northwestern portion of Pasadena, California. They describe the Center's property as a 35,751 square foot retail center, originally constructed in 1959, fully occupied by 13 tenants, and consisting of one larger structure plus a small restaurant. Recognizing the existing tenant leases in effect, their opinion is that as of March 16, 1990, the fee simple market value of the Center's property was $4,750,000. Messrs. Buss and Baaden have years of experience in real-estate consulting and valuation (19 years for Mr. Buss and 5 years for Mr. Baaden), and each represents that he has no personal interest or bias toward the parties involved in the Center.

For its fiscal year ended April 30, 1990, the Center's net cash income in excess of expenses was $279,407. A cash flow projection for the Center for the period January 1, 1991 through December 31, 1995 shows that the Center's net cash flow for this period,

[1] Since David Klein is the sole stockholder and employee of Hudson Enterprises, the Plan sponsor, and the only participant in the Plan, the Plan is not subject to title I of the Act, pursuant to 29 CFR 2510.3-3(b) and (c)(1). However, the Plan is subject to Title II of the Act, which includes section 4975 of the Code.

after deducting operating expenses and debt service on both the Current Loan and the proposed loan, is anticipated to aggregate $1,663,987 ($281,852 in 1991, $307,502 in 1992, $332,807 in 1993, $359,561 in 1994, and $382,265 in 1995), assuming a yearly increase of 5% in base rental income, as provided in the Center's tenants' leases, and in common-area-maintenance-fee income. The applicants point out that as a 90% partner in the Center, the Plan sponsor is liable for 90% of the Center's debts. The Plan's sponsor's balance sheet shows total assets of $3,448,377.98 and total net worth of $3,241,065.28 as of September 30, 1990.

5. By letter dated February 28, 1990, Mark Engelman, President of BayMark Financial, Inc. stated that BayMark Financial, Inc. would be willing to arrange a five-year $475,000 loan providing for monthly payments of interest only at the rate of 13% p.a. and secured by a second trust deed on the Center's property, provided the unpaid balance under the Current Loan did not exceed $800,000 and is current at close of escrow. Mark Engelman subsequently advised that BayMark Financial, Inc. would have charged a 5% loan fee to arrange and fund said $475,000 loan. It is represented that neither Mark Engelman nor BayMark Financial, Inc. is related in any manner to the Plan sponsor, to David Klein, or to the Plan.

6. In summary, the applicant represents that the proposed transaction satisfies the exemption criteria set forth in section 408(a) of the Act because:

(a) The proposed loan will be secured by a second deed of trust on improved real property valued by qualified independent appraisers at approximately three times the sum of the amount of the proposed loan plus the balance due under the Current Loan;

(b) An independent commercial lender has stated that it would make a loan for more than the same amount and under the same conditions as the proposed loan;

(c) The proposed loan will be repaid over a 60-month period in equal monthly payments of principal and interest and permits the Center to pay more than the sum due at any time;

(d) As of September 30, 1990, the net worth ($3,241,065) of the Plan sponsor, who is liable for 90% of the Center's debts, substantially exceeded the sum ($1,182,091) of the unpaid balance due as of November 16, 1990 under the Current Loan plus the entire principal amount of the proposed loan; and

(e) The Plan's sole participant, who makes investment decisions for the Plan, has determined that the proposed loan is administratively feasible and in his interests as a Plan participant.

Notice to Interested Persons: As David Klein is the only participant in the Plan, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and hearing requests on the proposed exemption are due 30 days after the date of publication of this notice in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Mrs. Miriam Freund, of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Elko Regional Medical Center Profit Sharing Plan (the Plan), Located in Elko, Nevada

[Application No. D-8599]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed loan of $785,000 (the Loan) by the Plan to Elko Regional Medical Center (the Employer), the Plan sponsor and a party in interest with respect to the Plan, provided that the following conditions are satisfied:

(1) The terms of the Loan will be at least as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party;

(2) The outstanding balance plus accrued, but unpaid interest on the Loan will at no time exceed 25% of the Plan's net assets;

(3) The independent fiduciary, who has represented that the transaction is in the best interest and protective of the Plan, will monitor the Loan and enforce the rights of the Plan under the Loan throughout its duration;

(4) The independent fiduciary is independent of other parties involved in the transaction and the fees received by the independent fiduciary for serving in such capacity, combined with any other fees derived from the Employer or related parties, will not exceed 1% of his annual income for each fiscal year that he continues to serve in the independent fiduciary capacity with respect to the transaction described herein; and

(5) On the date the Loan is entered into, the Plan will be named as the beneficiary and loss payee with respect to the fire and casualty insurance coverage on the commercial building (the Building), which secures the Note.

EFFECTIVE DATE: If granted this exemption will be effective as of July 1, 1991.

Summary of Facts and Representations

1. The Plan, established August 31, 1972, is a defined contribution profit sharing plan, which as of December 31 1990, had $3,227,314 in net assets. The trustees of the Plan are David M. Hogle, M.D., Emmalina G. Cortez, M.D. and George T. Manilla, M.D. (collectively, the Trustees). The Trustees are equal 7.14% shareholders and employees of the Employer, and David M. Hogle, M.D. is also the vice-president of the Employer. The Employer is a Nevada corporation, which is in the business of providing medical services to the public.

2. On October 24, 1983, the Employer borrowed $835,000 under a corporate demand note (Employer Loan 1) from the First Interstate Bank (the Bank), a third party lender. Employer Loan 1 has a floating interest rate of 1% over the prime lending rate (PL Rate) charged by the Bank, and is amortized on the basis of a 25 year schedule with a final balloon payment of unpaid principal and any accrued, unpaid interest due on July 1, 1991. Any changes in payment due to the change in PL Rate are consolidated and accounted for at the time the balloon payment comes due on July 1, 1991. On July 2, 1984, the Employer borrowed an additional $73,000 (Employer Loan 2; collectively, the Employer Loans) also from the Bank. The terms of Employer Loan 2 are the same as those of Employer Loan 1. The Employer Loans were utilized for the construction and improvement of the Building, which is used by the Employer as a primary place of business. The Building is utilized as security for the Employer Loans to the Bank.

3. The applicant proposes that effective July 1, 1991, the Employer be permitted to borrow $785,000 from the Plan. The Loan will enable the Employer to repay the Employer Loans with the Bank. Upon retirement of the Employer Loans, the Building will be utilized as collateral for the Loan from the Plan. A promissory note (the Promissory Note) will be issued by the Employer to the Plan, which evidences that the Loan will be secured by the first deed of trust mortgage on the Building. The applicant represents that with respect to the proposed Loan, the Plan will invest approximately 24% of its net assets and that the Plan will pay no expenses associated with the transaction. The applicant has also agreed that on the

date the Loan is entered into, the Plan will be named as the beneficiary and loss payee with respect to the fire and casualty insurance on the Building.

4. The applicant states that on the date the Loan is entered into, the Promissory Note will include a certain provision with respect to the interest rate (the Rate) involved in this transaction. Specifically, the Rate charged on the principal balance of the Loan will fluctuate in accordance with the prime lending rate (TPB Rate) charged by the Valley Bank of Nevada (Valley Bank), an independent third party bank, but always will be 1.5% above the TPB Rate. The Rate shall increase or decrease periodically and such change will be effective on the day the TPB Rate fluctuates.

5. The Loan will be payable in equal installments of principal and interest over the fifteen year term of the Loan. Because the TPB Rate and the Rate will fluctuate, the monthly payment will be re-computed to reflect this fluctuation. The re-computation will consider each fluctuation of the TPB Rate during a given year. These revisions will commence on July 1, 1992, and will continue to occur annually, on each anniversary date of the making of the Promissory Note. The upward or downward fluctuation of the Rate will have specific repercussions with respect to the payment structure of the Loan. Any increase in the Rate will be paid at the end of the year as an additional payment applied to the interest. The remaining principal will be calculated to amortize the balance over the remaining term of the Promissory Note, and to calculate the new monthly payment amount, which will be paid starting with the payment due at the beginning of the following month. Any decrease in the Rate during a payment year will be applied to reduce the principal balance to reflect the lowered interest rate. At the end of the payment year, the remaining balance will be used to calculate the payments for the next year. The Promissory Note provides that the Loan will be fully paid on or before July 31, 2006. The Promissory Note further provides for no penalty or bonus in the event of prepayment, and no loan fees, such as points, or other fees will be charged.

6. The appraisal of the Building (the Appraisal) was prepared by Bill Moschetti and John Moschetti, independent and qualified real estate appraisers with Moschetti & Barnhart appraisal section (the Appraisers). The Building, which contains a main floor of 17,185 square feet and a basement of 16,259 square feet, is located at 762 14th Street, Elko, Nevada. The appraisers primarily relied on the income and cost appraisal methods, and concluded that as of November 30, 1990, the fair market value of the Building was $2,500,000. On the first day of the fifth and tenth year of the Loan, the Appraisal of the Building will be updated. The Promissory Note provides that in the event the value of the Building falls below 150% of the loan to value ratio at any time during the term of the Loan, the independent fiduciary, as noted below, will contact the Employer to grant a security interest in other property with sufficient value to meet the 150% requirement.

7. Mr. Lester G. Preader II (Mr. Preader), a certified public accountant since October 1975 and a managing shareholder of Lester G. Preader II, Ltd., CPA, will serve as an independent fiduciary with respect to the proposed transaction. Mr. Preader represents that he is independent of all parties involved in the transaction and that he has no prior professional or personal association with any of the parties. Mr. Preader also maintains that the fees received by him for serving in the independent fiduciary capacity in this transaction, combined with any other fees derived from the Employer or related parties, will not exceed 1% of his annual income for each fiscal year that he continues to serve in the independent fiduciary capacity with respect to the transaction described herein.

8. Mr. Preader further represents that he is qualified to serve in the independent fiduciary capacity in this transaction due to his professional experience as a certified public accountant and due to his experience in providing administrative services to private pension Plans. Specifically, with respect to his other clients, Mr. Preader prepared retirement plan filings, investment alternatives and contribution calculations.

9. Mr. Preader states that he understands and accepts the duties and responsibilities of an ERISA fiduciary. In his capacity as an independent fiduciary, he will verify and monitor the closing of the Loan, thereby assuring that the Loan is adequately secured.[2] On the first day of the fifth and tenth year of the Loan, the Appraisal will be updated to assure that the loan to value ratio of the collateral remains in excess of 150%. Mr. Preader also states that if the loan to value ratio falls below 150% at any time during the Loan term, he will immediately contact the Employer for additional collateral in the form of real or personal property. Furthermore, the Loan structure requires that the Rate will change automatically as the TPB Rate changes, and accordingly Mr. Preader will monitor the annual re-computation of Loan payments to the Plan for any changes in TPB Rate for the year.

10. Mr. Preader notes that he has surveyed the current real estate loan market and financing guidelines and has concluded that the proposed Loan is comparable in terms of duration, interest rate and security provided, with other commercial loans being granted to borrowers of similar credit worthiness. He further represents that the Loan is in the best interest and protective of the Plan because the investment offers a high rate of return with low risk, is fully secured by the Building, and provides economic stability over the fifteen year term. The transaction can be easily monitored and verified over the duration of the Loan. Valley Bank, an independent financial institution, has also reviewed the Loan and confirmed that its terms are similar to those required by Valley Bank when making a comparable loan, provided that the borrower is credit worthy.

11. In summary, the applicant represents that the proposed transaction satisfies the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because:

(a) The Rate will fluctuate in accordance with the TPB Rate, but always will be 1.5% above the TPB Rate;

(b) The Loan will be adequately secured by the first deed of trust mortgage on the Building;

(c) The Appraisal will be updated on the first day of the fifth and tenth year of the Loan;

(d) The loan to value ratio of the collateral will always remain at least 150% of the Loan amount;

(e) The outstanding principal balance plus accrued, but unpaid interest on the Loan will at no time exceed 25% of the Plan's net assets;

(f) The Plan will bear no costs or commissions with respect to the proposed transaction; and

(g) The proposed terms of the Loan were evaluated by an independent fiduciary who deemed the transaction to be in the best interest and protective of the Plan, and who will also monitor the terms of the Loan over its duration.

FOR FURTHER INFORMATION CONTACT: Ekaterina A. Uzlyan of the Department, telephone (202) 523-8883. (This is not a toll-free number.)

[2] In this regard, Mr. Preader has informed the Department that with respect to the Employer Loans, the Employer has made timely payments to the Bank.

Schneider Transport, Inc. 401K Savings Plan (the 401K Plan), Special Services Division Retirement and Savings Plan (the R&S Plan) and Schneider National Retirement Plan (the SNI Plan; collectively, the Plans), Located in Green Bay, Wisconsin

[Application Nos. D-8750, D-8751 & D-8752]

PROPOSED EXEMPTION

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply, effective June 28, 1991, to the cash sale by the Plans of a guaranteed investment contract (the GIC) to Schneider National, Inc. (SNI), a party in interest with respect to the Plans; provided that the purchase price for the GIC was no less than its fair market value as of the date of the sale.

EFFECTIVE DATE: This exemption, if granted, shall be effective as of June 28, 1991.

Summary of Facts and Representations

1. The Plans are defined contribution pension plans sponsored by SNI and its wholly-owned subsidiary, Schneider Transport, Inc. All assets of the Plans are held in one master trust (the Trust), with total Plan assets of $21,643,418.94 as of May 31, 1991. As of December 31, 1990 there were 4,446 participants of the Plans. SNI is a Wisconsin privately-held corporation engaged in the commercial transport business in Green Bay, Wisconsin. The trustee of the trust is the Marshall & Ilsely Trust Company in Milwaukee, Wisconsin (the Trustee).

2. The assets of the Plans in the Trust include the GIC, a guaranteed investment contract issued as contract number 01207 by Executive Life Insurance Company of California (Executive Life) on January 2, 1987 for an initial cash deposit by the Trust of $488,223.31. Additional amounts were deposited pursuant to the GIC, which included a premium deposit limit of $1.3 million and a guaranteed interest rate of 8.25 percent compounded annually, with a maturity date of January 1, 1992. Participation in the GIC is allocated among the Plans according to each Plan's proportionate participation in the Trust. The percentage participation in the GIC is allocated among the Plans as follows:

(1) The 401K Plan: 2.4 percent;
(2) The R&S Plan: 10.6 percent;
(3) The SNI Plan: 87.0 percent.

According to an accounting by Executive Life on May 31, 1991, the balance of principal deposits plus accrued interest, less withdrawals, under the GIC was $2,080,153.05. SNI represents that this balance, referred to as book value, had increased to $2,093,024 as of June 28, 1991.

3. SNI represents that the Standard & Poors Rating (the S&P Rating) of Executive Life was AAA at the time of the Trust's acquisition of the GIC. During 1990 Executive Life's S&P rating dropped to BBB.[3] On April 12, 1991 Executive Life was placed into conservatorship by the California Insurance Commissioner and on April 17, 1991 the New York State Insurance Commissioner took into conservatorship Executive Life of New York. As a result of these developments, SNI questions the ability of Executive Life to honor its obligations with respect to the GIC. In order to relieve the Plans of risks associated with continued holding of the GIC, SNI purchased the GIC from the Trust on June 28, 1991 and is requesting an exemption to permit such transaction under the terms and conditions described herein.

4. SNI purchased the GIC from the Trust by paying the Trust cash in the amount of the GIC's book value as of the date of purchase.[4] The Trustee states that the book value of the GIC is the total amount deposited under the terms of the GIC plus accrued interest as provided by the GIC less any withdrawals from the GIC previously made by the Trust. The Trustee represents that the Trust had made no withdrawals from the GIC and that the Trust did not incur any expenses with respect to the transaction. SNI represents that its purchase of the GIC from the Trust is intended to eliminate the risks associated with continued holding of the GIC while enabling the Trust to redirect the assets invested in the GIC to safer investments and that the Plans have sustained no loss as a result of the transaction. The Trustee represents that it has investigated Executive Life's standing as an insurer and issuer of guaranteed investment contracts and has determined that under prevailing circumstances it was appropriate for the Plans to divest of the GIC. The Trustee states that SNI's purchase of the GIC was in the best interests of the participants and beneficiaries of the Plans and will protect them from loss and provide an opportunity for reinvestment. The Trustee represents that it has determined that the purchase price of the GIC at its book value was equal to or in excess of the GIC's fair market value on the sale date.

5. In summary, the applicant represents that the transaction satisfies the criteria of section 408(a) of the Act for the following reasons: (1) The Plans received cash for the GIC in the amount of the book value of the GIC as of the sale date, which the Trustee has determined to be equal to or in excess of the fair market value of the GIC; (2) The transaction enables the Plans to avoid any risk associated with continued holding of the GIC and to redirect the Plans' assets to safer investments; (3) The Plans did not incur any expenses or suffer any loss with respect to the transaction; and (4) The Trustee has determined that the Plans' sale of the GIC to SNI at book value was in the best interests of the participants and beneficiaries of the Plans.

FOR FURTHER INFORMATION CONTACT: Ronald Willett of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

Reynolds Metals Company Savings and Investment Plan for Salaried Employees (the Plan), Located in Richmond, Virginia

[Application No. D-8757]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, August 10, 1990). If the exemption is granted the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to an interest-free extension of credit to the Plan (the Advances) by Reynolds Metals Company (the Employer), the sponsor of the Plan; provided that (a) no interest and/or expenses are paid by the Plan; (b) the proceeds of the Advances are used only in lieu of payments due with respect to guaranteed investment contract number GIC01132 (the GIC) issued by Executive Life Insurance Company (Executive Life); (c)

[3] The Department expresses no opinion as to whether the Plans' investment in the GIC satisfied the fiduciary responsibility standards set forth in Part 4 of title I of the Act.

[4] SNI represents that the transaction was in compliance with section 415 of the Code.

repayment of the Advances will be restricted to cash proceeds paid to the Plan by or on behalf of Executive Life with respect to Executive Life's obligations under the GIC; and (d) repayment of the Advances will be waived to the extent the Plan receives less from the disposition of the GIC than the total amount of the Advances.

Summary of Facts and Representations

1. The Plan is a defined contribution plan which provides for individually-directed participant accounts (the Accounts). As of May 31, 1991 the Plan had approximately 6,288 participants and total assets of approximately $291,540,000. The trustee of the Plan is Sovran Bank of Richmond, Virginia (the Trustee). The Employer is a publicly-owned Delaware corporation engaged in the production of aluminum, aluminum products, other metals and packaging, with its principal place of business in Richmond, Virginia.

2. Participant contributions to the Plan are maintained in the Accounts and are invested according to each participant's directions into any of four investment funds (the Investment Funds), including a guaranteed investment fund (the GI Fund), which includes the GIC among its assets. Subject to certain restrictions, the Plan provides that once each calendar year participants may elect to transfer all or part of their Account balances from one Investment Fund to another. Four potential events under the Plan require an asset withdrawal from an Investment Fund: (1) Interfund transfers upon participant direction; (2) distributions upon termination of employment; (3) hardship or ordinary withdrawals during active employment; and (4) loans (collectively, Fund Withdrawals).

3. The GI Fund holds guaranteed investment contracts (the Contracts) issued by thirteen insurance companies. The Accounts participating in the GI Fund share a blended rate of interest resulting from pro rata allocation of such participating Accounts among all the Contracts. Fund Withdrawals from the GI Fund are allocated exery six months pro rata among the Contracts on the basis of each Contract's accumulated book value." [5] The Contracts include the GIC, which was issued by Executive Life on July 1, 1986. The GIC provides for a guaranteed interest rate of 8.45 percent compounded annually over four years, with an initial principal deposit of $500,000 and no deposit limit." [6] Originally, the GIC provided for no payments until maturity on July 1, 1992, but it was restructured at the request of the GI Fund on July 24, 1990 to provide for four maturity payment dates: March 1, May 1, September 1 and November 1, 1992. As of May 3, 1991 the GIC had an accumulated book value of $11,400,378, representing approximately 3.91 percent of the Plan's assets and approximately 11.70 percent of the assets in the GI Fund.

4. On April 12, 1991 Executive Life was placed into conservatorship by the California Insurance Commissioner. The Employer represents that Executive Life ceased payments on contracts such as the GIC upon the commencement of the conservatorships. In a May 21, 1991 announcement of a proposed rehabilitation plan for Executive Life (the Rehab Plan), the California Insurance Commissioner indicated that the Rehab Plan would occur over three to five years, and possibly longer. The Employer maintains that under the prevailing circumstances it is doubtful that Executive Life will make timely payment to the GI Fund pursuant to the GIC for (1) its pro rata share of Fund Withdrawals, and (2) the four maturity payments in 1992. The Employer has notified Plan participants that it would undertake measures to ensure that the GI Fund receives the amounts due under the GIC. In order to proceed on this assurance, and to protect the participants from any adverse effects of nonpayment on the GIC or a possibly prolonged Rehab Plan, the Employer proposes the Advances as interest-free loans to the Plan. The Advances will be made at such times and in such amounts as would be required under the terms of the GIC. An exemption is requested by the Employer to permit the Advances under the terms and conditions described herein.

5. The Employer represents that the Advances are proposed as an effective method for placing the Plan in the same financial position it would have been in without Executive Life's adverse developments, while ensuring preservation of the Plan's rights of recovery from Executive Life or any sources making payments on behalf of Executive Life. The Advances will be made pursuant to a written agreement between the Employer and the Plan (the Agreement) embodying all terms of the extension of credit and its repayment. The Agreement provides that if, at any time, Executive Life fails to pay to the Plan any amounts due in accordance with the terms of the GIC, then the Employer will advance to the Plan the difference between the amount due to the Plan under the GIC and the amount paid to the Plan, if any, when such payment is due under the GIC. The Plan is required to notify the Employer promptly of any failure by Executive Life to make any payment due under the GIC, and the Employer is required to transfer to the Plan funds in the amount of the appropriate Advance under the Agreement within three days of such notice.

Repayment of the Advances under the Agreement is limited to payments made to the Plan pursuant to the GIC by Executive Life or by any conservator, trustee or other person performing similar functions with respect to Executive Life, or by any state guaranty fund or other person or entity, other than the Employer, acting as a surety or insurer with respect to Executive Life. No other Plan assets will be available for repayment of the Advances. If payments by or on behalf of Executive Life are not sufficient to repay fully the Advances, the Agreement provides that the Employer will have no recourse against the Plan, or against any participants or beneficiaries of the Plan, for the unpaid amount.[7] To the extent the Plan receives amounts with respect to the GIC from or on behalf of Executive Life in excess of the total amount of Advances, such additional amounts will be retained by the Plan and allocated among the accounts of participants in the GI Fund.

With respect to any GIC payment received by the Plan at a time when no payment is scheduled under the GIC, the Agreement provides that such payment shall be applied (1) first to reduce the accumulated book value of the GIC, and (2) then to repayment of Advances under the Agreement, but only after all amounts due the Plan under the GIC have been received by the Plan.

6. In summary, the applicant represents that the proposed transaction satisfies the criteria of section 408(a) of the Act for the following reasons: (1) The Advances will preserve the Plan's rights with respect to the GIC and enable the Plan to remain in the same position which would result from full and timely performance under the GIC by Executive Life; (2) The Plan will pay no interest or incur any expenses with

[5] The applicant represents that the accumulated book value of a Contract is equal to the total premium deposits made under the Contract plus accrued interest less any withdrawals made under the Contract.

[6] The Department expresses no opinion as to whether the acquisition of the GIC satisfied the fiduciary responsibility standards of part 4 of title I of the Act.

[7] The Employer represents that the Plan will comply with section 415 of the Code as a result of the transaction, including any waiver of repayment of the Advances.

respect to the Advances; (3) Repayment of the Advances will be restricted to payments by or on behalf of Executive Life with respect to the GIC and no other Plan assets will be involved in the transactions; and (4) Repayment of the Advances will be waived to the extent the Plan recoups less from or on behalf of Executive Life on the disposition of the GIC than the total amount of the Advances.

FOR FURTHER INFORMATION CONTACT: Ronald Willett of the Department telephone (202)523-8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 17th day of July, 1991.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 91-17367 Filed 7-19-91; 8:45 am]

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[Prohibited Transaction Exemption 91-39; Exemption Application No. D-7755]

Grant of Individual Exemptions; Department of Veterans Affairs

AGENCY: Pension and Welfare Benefit Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Department of Veterans Affairs

[Prohibited Transaction Exemption 91-39; Exemption Application Number D-7755]

Exemption

I. Transactions—Retroactive Relief

A. Effective for trusts closed on or after June 29, 1988 and on or before July 22, 1991, the restrictions of sections 406(a) and 407 of the Employee Retirement Income Security Act of 1974 (the Act) and the taxes imposed by section 4975 (a) and (b) of the Internal Revenue Code of 1986 (the Code) by reason of section 4975 (c)(1)(A) through (D) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and an employee benefit plan (plan) when the sponsor, servicer, trustee or insurer of a trust, or the underwriter of the certificates representing an interest in the trust, is a party in interest with respect to such plan, provided that the plan pays no more than fair market value for such certificates, and provided further that the rights and interests evidenced by such certificates are not subordinated to the rights and interests evidenced by other certificates of the same trust;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates; and

(3) The continued holding of certificates acquired pursuant to subparagraph (1) or (2) above, by an employee benefit plan.

B. Effective for trusts closed on or after June 29, 1988 and on or before July 22, 1991, the restrictions of sections 406(b)(1) and (2) and 407 of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section

4975(c)(1)(E) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter of a trust and an employee benefit plan when the sponsor, servicer, trustee or insurer of such trust or the underwriter of the certificates representing an interest in the trust, is a fiduciary with respect to the plan assets invested in such certificates provided:

(a) Such sale, exchange or transfer is expressly approved by a fiduciary independent of the sponsor, servicer, trustee, insurer or underwriter who has authority to manage and control those plan assets being invested in such certificates;

(b) The plan pays no more for the certificates than would be paid in an arm's length transaction with an unrelated party;

(c) No investment management, advisory, or underwriting fee or sales commission or similar compensation is paid to the sponsor or underwriter with regard to such sale, exchange or transfer;

(d) The total value of certificates purchased by a plan does not exceed 25% of the amount of the issue; and

(e) At least 50% of the aggregate amount of the issue is acquired by persons independent of the pool sponsor, servicer, trustee, insurer or underwriter.

(C) Effective for trusts closed on or after June 29, 1988 and or before July 22, 1991, the restrictions of sections 406(a) and (b) and 407 of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c) of the Code shall not apply to transactions in connection with the servicing, management, and operation of a trust provided that:

(1) Such transactions are carried out in accordance with the terms of a binding pooling and servicing agreement; and

(2) The pooling and servicing agreement is provided to, or described in all material respects in the prospectus provided to, investing plans before they purchase certificates issued by the trust.

(D) Effective for trusts closed on or after June 29, 1988 and on or before July 22, 1991, the restrictions of sections 406(a) and 407 of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975 (c)(1) (A) through (D) of the Code shall not apply to any transactions to which such restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest or disqualified person (including a fiduciary) with respect to a plan by virtue of providing services to the plan (or by virtue of having a relationship to such service provider described in section 3(14) (F), (G), (H) or (I) of the Act or section 4975 (e)(2)(F), (G), (H) or (I) of the Code), solely because of the plan's ownership of certificates.

II. General Conditions for Transactions Described in Part I

A. The relief provided under part I, above, is available only if the following conditions are met:

(1) The sponsor and trustee for each trust must maintain a system for insuring or otherwise protecting the pooled mortgage loans and the property securing such loans, and for indemnifying certificateholders against reductions in pass-through payments due to defaults in loan payments or property damage. (The term "mortgage" is used herein to refer not only to mortgages but also to deeds of trust and installment contracts for the sale of real estate.) This system must provide such protection and indemnification up to an amount not less than the greater of one percent of the aggregate principal balance of all covered pooled mortgages, or the principal balance of the largest covered mortgage;

(2) The trustee for each trust must not be an affiliate of the servicer of such trust, provided, however, that the trustee shall not be considered to be an affiliate of the servicer solely because the trustee has succeeded to the rights and responsibilities of the servicer pursuant to the terms of the pooling and servicing agreement providing for such succession upon the occurrence of one or more events of default by the servicer; and

(3) The sum of all payments made to and retained by the underwriters in connection with the distribution or placement of certificates represents not more than reasonable compensation for underwriting or placing the certificates; the sum of all payments made to and retained by the sponsor pursuant to the assignment of obligations (or interests therein) to the trust represents not more than the fair market value of such obligations (or interests); and the sum of all payments made to and retained by the servicer represents not more than reasonable compensation for the servicer's services under the pooling and servicing agreement and reimbursement of the servicer's reasonable expenses in connection therewith.

III. Transactions—Prospective Relief

A. Effective for trusts closed after July 22, 1991, the restrictions of sections 406(a) and 407 of the Act and the taxes imposed by section 4975 (a) and (b) of the code by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and an employee benefit plan (plan) when the sponsor, servicer, the trustee of a trust, or the underwriter of the certificates representing an interest in the trust or an obligor is a party-in-interest with respect to such plan;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates; and

(3) The continued holding of certificates acquired by a plan pursuant to subparagraph (1) or (2).

B. Effective for trusts closed after July 22, 1991, the restrictions of sections 406 (a) and (b) and 407 of the Act, and the taxes imposed by section 4975 (a) and (b) of the code by reason of section 4975(c) of the Code, shall not apply to transactions in connection with the servicing, management and operation of a trust provided that:

(1) Such transactions are carried out in accordance with the terms of a binding pooling and servicing agreement; and

(2) The pooling and servicing agreement is provided to, or described in all material respects in the prospectus provided to, investing plans before they purchase certificates issued by the trust.

Notwithstanding the foregoing, section III.B. does not provide an exemption from the restrictions of sections 406(b) and 407 of the Act or from the taxes imposed by reason of section 4975(c) of the Code for the receipt of a fee by a servicer of the trust from a person other than the trustee or sponsor, unless such fee constitutes a "qualified administrative fee" as defined in section V.O.

C. Effective for trusts closed after July 22, 1991, the restrictions of sections 406(a) and 407 of the Act, and the taxes imposed by sections 4975 (a) and (b) of the code by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to any transactions to which such restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest or disqualified person (including a fiduciary) with respect to a plan by virtue of providing services to the plan (or by virtue of having a relationship to such service provider described in

section 3(14) (F), (G), (H) or (I) of the Act or section 4975(e)(2) (F), (G), (H) or (I) of the Code), solely because of the plan's ownership of certificates.

IV. General Conditions for Transactions Described in Part III

A. The relief provided under part III is available only if the following conditions are met:

(1) The acquisition of certificates by a plan is on terms (including the certificate price) that are at least as favorable to the plan as they would be in an arm's-length transaction with an unrelated party;

(2) The rights and interests evidenced by the certificates are not subordinated to the rights and interests evidenced by other certificates of the same trust. In the case of a double REMIC structure, the rights and interests evidenced by the certificates held by an issuing REMIC are also not subordinated to the rights and interests evidenced by other certificates of the pooling REMIC;

(3) The certificates acquired by the plan have received a rating at the time of such acquisition that is in one of the three highest generic rating categories from either Standard & Poor's Corporation (S&P's), Moody's Investors Service, Inc. (Moody's), Duff & Phelps, Inc. (D & P) or Fitch Investors Service, Inc. (Fitch);

(4) The trustee is not an affiliate of any member of the Restricted Group. However, the trustee shall not be considered to be an affiliate of the servicer solely because the trustee has succeeded to the rights and responsibilities of the servicer pursuant to the terms of a pooling and servicing agreement providing for such succession upon the occurrence of one or more events of default by the servicer; and

(5) The sum of all payments made to and retained by the underwriters in connection with the distribution of certificates represents not more than reasonable compensation for underwriting the certificates; the sum of all payments made to and retained by the sponsor pursuant to the assignment of obligations (or interests therein) to the trusts represents not more than the fair market value of such obligations (or interests); and the sum of all payments made to and retained by the servicer represents not more than reasonable compensation for the servicer's services under the pooling and servicing agreement and reimbursement of the servicer's reasonable expenses in connection therewith.

(6) The plan investing in such certificates is an "accredited investor" as defined in Rule 501(a)(1) of Regulation D of the Securities and Exchange Commission under the Securities Act of 1933.

B. Neither any underwriter, sponsor, trustee or servicer, unless it or any of its affiliates has discretionary authority or renders investment advice with respect to the plan assets used by a plan to acquire certificates, shall be denied the relief provided under part III, if the provision of subsection IV.A.(6) above is not satisfied with respect to the acquisition or holding by a plan of such certificates, provided that such condition is disclosed in the prospectus.

V. Definitions

For purposes of this exemption:

A. *Certificate* means:

(1) A certificate

(a) That represents a beneficial ownership interest in the assets of a trust; and

(b) That entitles the holder to pass-through payments of principal, interest, and/or other payments made with respect to the assets of such trust; or

(2) A certificate denominated as a debt instrument

(a) That represents an interest in a Real Estate Mortgage Investment Conduit (REMIC) within the meaning of section 860D(a) of the Code; and

(b) That is issued by and is an obligation of a trust; and

(3) With respect to the transactions described in part III, a certificate that represents an interest in obligations which are subject to a guaranty issued by the VA of all of the principal and interest due on the obligations.

For purposes of this exemption, references to "certificates representing an interest in a trust" include certificates denominated as debt which are issued by a trust.

B. *VA guaranty* means a guaranty by the VA of all or a portion of the principal and interest on the obligations contained in a trust as set forth in the loan sale agreement entered into the VA and a trustee with respect to the obligations contained in the trust.

C. *Trust* means an investment pool, the corpus of which is held in trust and consists solely of:

(1) Obligations that bear interest and which are secured by first mortgages, deeds of trust or installment contracts on single-family, residential property;

(2) Fractional undivided interests in any of the obligations described in subsection (1);

(3) Property which had secured any of the obligations described in subsection (1);

(4) Undistributed cash or temporary investments made therewith maturing no later than the next date on which distributions are made to certificateholders;

(5) Rights of the trustee under the pooling and servicing agreement and the loan sale agreement including rights under the VA guaranty with respect to any obligations described in subsection (1); and

(6) Interests in a second investment pool, the corpus of which is held in trust and consists solely of any of the obligations and other property listed in clauses (1) through (5).

Notwithstanding the foregoing, with respect to transactions described in part III, the term "trust" does not include any investment pool unless:

(i) The investment pool consists only of assets of the type which have been included in other investment pools,

(ii) Certificates evidencing interests in such other investment pools have been rated in one of the three highest rating categories by S & P's, Moody's, D & P or Fitch for at least one year prior to the plan's acquisition of certificates pursuant to this exemption, and

(iii) Certificates evidencing interests in such other investment pools have been purchased by investors other than plans for at least one year prior to the plan's acquisition of certificates pursuant to this exemption.

D. *Underwriter* means:

(1) Any person designated by the VA to act as a managing or co-managing underwriter with respect to the certificates;

(2) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with a person described in (1); or

(3) Any member of an underwriting syndicate or selling group of which a person described in (1) or (2) is a manager or co-manager with respect to the certificates.

E. *Sponsor* means the United States Department of Veterans Affairs.

F. *Servicer* means the entity [i.e., master servicer] that is a party to the pooling and servicing agreement relating to trust assets and is fully responsible for servicing, directly or through sub-servicers, the assets of the trust. The term servicer includes sub-servicers which, under the supervision of and on behalf of the master servicer, service loans contained in the trust, but are not parties to the pooling and servicing agreement.

G. *Trustee* means the trustee of the trust, and in the case of certificates which are denominated as debt instruments, also means the trustee of the indenture trust.

H. *Restricted Group* with respect to a class of certificates means:

(1) Each underwriter;

(2) The sponsor;

(3) The trustee;

(4) Each servicer; and

(5) Any affiliate of a person described in (1)–(4) above.

I. *Affiliate* of another person includes:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director, partner, employee or relative (as defined in section 3(15) of the Act), a brother, a sister, or a spouse of a brother or sister of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director or partner.

J. *Control* means the power to exercise a controlling influence over the management or policies of a person other than an individual.

K. A person will be "independent" of another person only if:

(1) Such person is not an affiliate of that other person; and

(2) The other person, or an affiliate thereof, is not a fiduciary who has investment management authority or renders investment advice with respect to any of the assets of such person.

L. *Sale* includes the entrance into a forward delivery commitment (as defined in paragraph M below) provided that:

(1) The terms of the forward delivery commitment (including any fee paid to the investing plan) are no less favorable to the plan than they would be in an arm's-length transaction with an unrelated party;

(2) The prospectus is provided to an investing plan prior to the time the plan enters into the forward delivery commitment; and

(3) At the time of the delivery, all conditions of this exemption applicable to sales are met.

M. *Forward delivery commitment* means a contract for the purchase or sale of one or more certificates to be delivered at an agreed future settlement date. The term includes both mandatory contracts (which contemplate obligatory delivery and acceptance of the certificates) and optional contracts (which give one party the right but not the obligation to deliver certificates to, or demand delivery of certificates from, the other party).

N. *Reasonable compensation* has the same meaning as that term is defined in 29 CFR 2550.408c–2.

O. *Qualified Administrative Fee* means a fee which meets the following criteria:

(1) The fee is triggered by an act or failure to act by the obligor other than the making of normal timely payment of amounts owing in respect of the obligations;

(2) The servicer may not charge the fee absent the act or failure to act referred to in (1);

(3) The ability to charge the fee, the circumstances in which the fee may be charged, and an explanation of how the fee is calculated are set forth in the pooling and servicing agreement; and

(4) The amount paid to investors in the trust will not be reduced by the amount of any such fee waived by the servicer.

P. *Pooling and Servicing Agreement* means the agreement or agreements among a sponsor, a servicer and the trustee establishing a trust. In the case of certificates which are denominated as debt instruments, "Pooling and Servicing Agreement" also includes the indenture entered into by the trustee of the trust issuing such certificates and the indenture trustee.

Q. *Loan Sale Agreement* means the agreement between the VA and the Trustee under which the VA conveys legal title to the obligations to be contained in the trust in exchange for the net proceeds from the sale of the certificates issued pursuant to the related pooling and servicing agreement. The VA makes representations and warranties with respect to these obligations in the loan sale agreement.

R. *Single-family, Residential Property* means non-farm property comprising one to four dwelling units, and also includes condominiums.

Written Comments: The Department received one comment with regard to the proposed exemption. It is discussed below.

Applicant Comments

The applicant raised two issues regarding the proposed exemption. Section V.C. of the proposed exemption defines "Trust" in part, as "an investment pool, the corpus of which is held in trust and consists solely of * * *

(5) Fractional undivided interests in any of the obligations and other property listed in clauses (1) through (4)."

The applicant expressed concern that the proposed exemption would not permit the use of "double REMIC" structures. In a "double REMIC" structure, a "pooling REMIC" is formed and issues one or more classes of regular interests and a single class of residual interests. Some or all of the classes of regular interests are transferred to a second REMIC (the "issuing REMIC") which also issues one or more classes of regular interests and a single class of residual interests. The classes of interests sold to investors are generally the interests in the issuing REMIC. However, regular interests not sold to the issuing, REMIC and the residual interests in the pooling REMIC may be sold to investors. The decision to structure a transaction as a double REMIC is made by the VA and the underwriter on the basis of tax, accounting and other regulatory consequences. The applicant has therefore requested that the definition of Trust under Section V. C. of the proposed exemption be modified to clarify that the final exemption will be available for the use of a double REMIC structure. After considering this comment, the Department has determined to clarify the definition of Trust in section V.C. of the final exemption to include "interests in a second investment pool, the corpus of which is held in trust and consists solely of any of the obligations and other property listed in clauses (1) through (5)." In this regard, the Department has also modified section IV. A. in the final exemption to clarify that the certificates held by the issuing REMIC may not be subordinated to the rights and interests evidenced by other certificates issued by the pooling REMIC.

The applicant further requested that the proposal be expanded to include interest rate swap contracts in the corpus of trusts subject to the exemption in order to facilitate the issuance by such trusts of floating rate certificates. On the basis of the record developed to date, the Department does not believe that it has a sufficient basis upon which to provide exemptive relief for interest rate swap contracts at this time. However, the Department wishes to note that the applicant may pursue further exemptive relief for interest rate swaps and, upon a proper showing, the Department would be prepared to consider additional relief, as appropriate.

After consideration of the entire record, the Department has determined to grant the exemption, as modified herein.

FOR FURTHER INFORMATION CONTACT: Deborah Hobbs of the Department of Labor at (202) 523–7901. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section

4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemptions do not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 17th day of July, 1991.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 91-17366 Filed 7-19-91; 8:45 am]

BILLING CODE 4510-29-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-602]

University of Texas; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an extension to the latest construction completion date specified in Construction Permit No. CPRR-123 issued to the University of Texas (UT or the applicant) for the TRIGA Mark III Research Reactor. The facility is located on the applicant's site at the University of Texas Balcones Research Center in Austin, Texas.

Environmental Assessment

Identification of Proposed Action

The proposed action would extend the latest construction completion date of Construction Permit No. CPRR-123 to October 31, 1991. The proposed action is in response to the applicant's request dated May 24, 1991.

The Need for the Proposed Action

The proposed action is needed to allow time to close open items identified by the Commission's inspection program and to allow time to complete review of the documentation required to support issuance of the Facility Operating License.

Environmental Impact of the Proposed Action

Since the proposed action involves extending the construction permit, there are no radiological impacts associated with this action. The impacts that are involved are all non-radiological and are associated with continued construction. The impact of construction was evaluated in the Environmental Assessment prepared as part of the NRC staff's review dated May 13, 1985, of the UT construction permit application.

Based on the foregoing, the NRC staff concludes that the proposed extension of the construction permit would have no significant environmental impact.

Alternatives Considered

Since we have concluded that there is no significant environmental impact associated with this construction permit extension, any alternatives will either have no significant impact or greater impact than the proposed action.

A possible alternative to the proposed action would be to deny the request. Under this alternative, the applicant would not be able to complete construction of the facility. This would result in denial of the benefit of research, education, and training. This option would not eliminate the environmental impacts of construction already incurred.

If construction were halted and not completed, site redress activities would restore small areas to their original state. This would be a slight environmental benefit, but much outweighed by the educational and economic losses from denial use of a facility that is nearly completed. Therefore, this alternative is rejected.

Another alternative is to take no action on the request for extension. The construction permit would not be deemed to have expired until the application has been finally processed (10 CFR 2.109). In effect the construction permit could be in effect as long as no action was taken on a timely application for extension. To take no action on the applicant's request would not be responsive; therefore, this alternative is rejected.

Alternative Use of Resources

This action does not involve the use of resources other than those evaluated in the Environmental Assessment prepared as part of the NRC staff's review dated May 13, 1985, of the UT construction permit application.

Agencies and Persons Consulted

The NRC staff reviewed the applicant's request and applicable documents referenced therein that support this extension. The NRC did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for this action. Based upon the environmental assessment, we conclude that this action will not have a significant effect on the quality of the human environment.

For details with respect to this action, see the request for extension dated May 24, 1991, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC 20555.

Dated at Rockville, Maryland this 15th day of July 1991.

For the Nuclear Regulatory Commission.

Seymour H. Weiss,

Non-Power Reactors, Decommissioning and Environmental Project Directorate, Division of Advanced Reactors and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 91-17357 Filed 7-19-91; 8:45 am]

BILLING CODE 7590-01-M

Draft Report on Chemical Form of Iodine in LWR Accidents

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability for comment of DRAFT NUREG/CR-5732, "Iodine Chemical Forms in LWR Accidents".

SUMMARY: This notice announces the availability for comment of draft NUREG/CR-5732, "Iodine Chemical Forms in LWR Accidents." The information in this report will be considered by the NRC staff in the formulation of updated accident source terms for LWR reactors to replace those given in report TID-14844. These source

terms are used in the licensing of nuclear power plants to assure adequate protection for the public health and safety.

Any interested party may submit comments on this report for consideration by the staff. To be certain of consideration, comments must be received within 45 days of the date of this **Federal Register** notice and should be sent to the contact indicated below. Comments received after this date will be considered to the extent practical.

A copy of draft NUREG/CR-5732 has been placed in the NRC Public Document Room, Gelman Building, 2120 L Street NW., Washington, DC 20555. A free single copy may be obtained by writing to the U.S. Nuclear Regulatory Commission, Attn: Distribution Section, 7103-MNBB, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Leonard Soffer, Office of Nuclear Regulatory Research Commission, Washington, DC 20555. Telephone (301) 492-3916.

Dated in Rockville, Maryland this 17th day of June, 1991.

For the Nuclear Regulatory Commission.

Warren Minners,

Director, Division of Safety Issue Resolution, Office of Nuclear Regulatory Research.

[FR Doc. 91-17353 Filed 7-19-91; 8:45 am]

BILLING CODE 7590-01-M

Availability of Draft Staff Technical Position on Geologic Repository Operations Area Underground Facility Design—Thermal Loads

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The Nuclear Regulatory Commission is announcing the availability of the draft staff technical position (STP) on "Geologic Repository Operations Area Underground Facility Design—Thermal Loads."

DATES: The comment period expires October 21, 1991.

ADDRESSES: Send comments to David L. Meyer, Chief, Regulatory Publications Branch, Division of Freedom of Information and Publication Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of this document may be obtained free of charge upon written request to Anne E. Garcia, Repository Licensing and Quality Assurance Project Directorate, Division of High-Level Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop 4-H-3, Washington, DC 20555. Telephone 301/492-0438. A copy of this draft STP is also available for public inspection and/or copying at the NRC Public Document Room, 2120 L. Street (Lower Level), NW., Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Michael P. Lee, Project Manager, Repository Licensing and Quality Assurance Project Directorate, Division of High-Level Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop 4-H-3, Washington, DC 20555. Telephone 301/492-0421.

SUPPLEMENTARY INFORMATION: Section 60.133(i) requires that the underground facility of a geologic repository be designed so that the 10 CFR part 60 performance objectives will be met, taking into account the predicted thermal and thermomechanical response of the host rock, surrounding strata, and groundwater system. This STP has been developed by the Division of High-Level Waste Management to provide regulatory guidance to the U.S. Department of Energy (DOE) on acceptable methodologies for demonstrating compliance with 10 CFR 60.133(i). The U.S. Nuclear Regulatory Commission (NRC) staff's position is that DOE should develop and use a defensible methodology to demonstrate the acceptability of a geologic repository operations area (GROA) facility design. The NRC staff currently anticipates that this methodology will require development of fully coupled models to account for the thermal, mechanical, hydrological, and chemical processes that are induced by the thermal load. The GROA underground facility design: (1) Should satisfy design goals/criteria initially selected by considering the performance objectives; and (2) must satisfy the performance objectives 10 CFR 60.111, 60.112, and 60.113. The methodology described in this STP suggest an iterative approach suitable for the underground facility design at the time of a license application.

Dated at Rockville, Maryland this 16th day of July, 1991.

For the Nuclear Regulatory Commission

B.J. Youngblood,

Director, Division of High-Level Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 91-17354 Filed 7-19-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos 50-498 and 50-499]

Houston Lighting & Power Co. et al; Operating Licenses

In the matter of Houston Lighting & Power Co., City Public Service Board of San Antonio, Central Power and Light Co., City of Austin, TX, South Texas Project, Units 1 and 2; Withdrawal of Amendments to Facility Operating Licenses.

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Houston Lighting & Power Company (the licensee) to withdraw two of the requested changes to the Technical Specifications that were included in the February 1, 1990, application for proposed amendments to Facility Operating Licenses NPF-76 and NPF-80 for the South Texas Project, Units 1 and 2, located in Matagorda County, Texas.

The February 1, 1990, application for amendments requested 22 changes to the Technical Specifications (TSs) based on a probabilistic risk analysis. The two withdrawn requests concern the power operated relief valves (TS section 3.4.4) and the Spray Additive System (TS section 3.6.2.2).

The Commission had previously issued a Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing published in the **Federal Register** on March 21, 1990 (55 FR 10535). However, by letter dated June 5, 1991, the licensee withdrew the aforementioned two changes.

For further details with respect to this action, see the application for amendments dated February 1, 1990, and the licensee's letter dated June 5, 1991, which withdrew the two requested changes. The above documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and the Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488.

Dated at Rockville, Maryland, this 15th day of July 1991.

For the Nuclear Regulatory Commission.

George F. Dick, Jr.,

Project Manager, Project Directorate IV-2, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 91-17355 Filed 7-19-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-445]

Texas Utilities Electric Co.; (Comanche Peak Steam Electric Station, Unit No. 1); Exemption

I

On April 17, 1990, the Commission issued Facility Operating License No. NPF-87 to Texas Utilities Electric Company, et al. (the licensee) for Comanche Peak Steam Electric Station, Unit No. 1. This license provided, among other things, that the facility is subject to all rules, regulations and Orders of the Commission.

II

Section 50.71(e)(3)(i) of title 10 of the Code of Federal Regulations requires the licensees of nuclear power reactors to submit an Updated Final Safety Analysis Report (UFSAR) within 24 months of either July 22, 1980, or the date of issuance of the operating license, whichever is later. This would require submittal of the UFSAR by April 17, 1992, and would result in an entirely new document from the existing Comanche Peak FSAR.

By letter dated April 1, 1991, the licensee requested an exemption from 10 CFR 50.71(e) which would defer submittal of the UFSAR until two years following receipt of a low-power operating license for Comanche Peak Steam Electric Station, Unit 2. The licensee states that it will continue to maintain the Comanche Peak Steam Electric Station FSAR as a description of both Units 1 and 2. The FSAR will be updated by periodic amendments during the period that Unit 2 is under construction, thus assuring that timely information regarding both units is provided.

III

The NRC staff has reviewed the licensee's request for an extension of the Comanche Peak Steam Electric Station, Unit No. 1, UFSAR submittal date. Section 50.34 of title 10 of the Code of Federal Regulations requires that, until Comanche Peak Steam Electric Station, Unit No. 2 receives an operating license, the information contained in the FSAR docketed with the operating license application be maintained current. Hence, if an extension to the submittal date for the UFSAR is not granted, the licensee would be required to maintain current both the present FSAR as well as the Unit 1 UFSAR until Comanche Peak Steam Electric Station, Unit No. 2 is licensed. Maintaining two versions of the same document for the two Comanche Peak Steam Electric Stations would not serve the underlying purpose of 10 CFR 50.71(e), which is to assure that the final safety analysis report contains the latest material developed. Thus, an undue administrative burden would be imposed which results in no measurable gain.

Therefore, an extension is needed to eliminate the hardship of maintaining two versions of the same document. Until Comanche Peak Steam Electric Station Unit No. 2 receives an operating license, the licensee has committed to maintain the present FSAR current for both units by periodically amending the document. This will assure that the underlying purpose of 10 CFR 50.71(e), i.e., assurance that the safety analysis report contains the latest material developed, continues to be met.

For these reasons, the staff finds that the licensee has shown good cause for the requested extension of the date for submittal of the Updated Final Safety Analysis Report. Therefore, the requested extension to no later than two years after issuance of a low-power license for Comanche Peak Steam Electric Station, Unit No. 2 is acceptable. This extension will terminate, unless further extended, no later than the end of December 1995.

IV

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a)(1), this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further detemines that special circumstances, as provided in 10 CFR 50.12(a)(2)(ii), are present justifying the exemption. The application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule in that the licensee has updated the Comanche Peak Steam Electric Station FSAR in support of licensing Comanche Peak Steam Electric Station, Unit No. 2, and will continue to update it periodically until Unit 2 is licensed.

Accordingly, the Commission hereby grants an exemption as described in section III above from 10 CFR 50.71(e)(3)(i) of 10 CFR Part 50 to extend the date for submittal of the updated FSAR to no later than two years after the date of issuance of a low-power license for Comanche Peak Steam Electric Station, Unit No. 2. This exemption is effective until the end of December 1995.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of the Exemption will have no significant impact on the environment (56 FR 24100).

This Exemption is effective upon issuance.

Dated at Rockville, Maryland, this 15th day of July 1991.

For the Nuclear Regulatory Commission.

Bruce A. Boger,

Director, Division of Reactor Projects—III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 91-17356 Filed 7-19-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-271]

Vermont Yankee Nuclear Power Corp.; Issuance of Amendment to Facility Operating License and Final Determination of no Significant Hazards Consideration

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 130 to Facility Operating License No. DPR-28 issued to Vermont Yankee Nuclear Power Corporation (the licensee), which authorizes the storage of 2870 assemblies in the spent fuel storage pool for the Vermont Yankee Nuclear Power Station located in Windham County, Vermont. The amendment is effective as of the date of issuance.

The amendment allows the storage of 2870 fuel assemblies in the spent fuel storage pool. The amendment is in response to the licensee's proposed application for amendment dated April 25, 1986, as supplemented on August 15, September 26, October 21, and November 24, 1986, and February 25, March 19, March 31, April 9, April 13, May 22, June 11, September 1, and December 11, 1987, March 2, 1988 and June 7, 1988 and September 28, 1990.

Notice of Consideration of Issuance of Amendment and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with this action was published in the **Federal Register** on June 18, 1986 (51FR22226) and again on December 31, 1986 (51FR47324).

Requests for a hearing were filed on January 29, 1987 by the New England Coalition on Nuclear Pollution (NECNP) and by the State of Vermont. On January 30, 1987 a request was filed by the Commonwealth of Massachusetts. NECNP and the Commonwealth were admitted as parties.

Following prehearing conferences, oral arguments, an agreement by all parties based on a stipulation, and the withdrawal of NECNP from the proceeding, the Commission terminated the proceeding by Order, dated September 21, 1990.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the supplemental Safety Evaluation related to this action. Accordingly, as described above, the amendment has been issued and made immediately effective.

The Commission published its Issuance of Environmental Assessment and Finding of No Significant Impact in the **Federal Register** on August 1, 1988 (53 FR 28925).

The Commission has determined that this amendment satisfies the criteria for categorical exclusion in accordance with 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared.

For further details with respect to the action, see (1) the application for amendment dated April 25, 1986, as supplemented by letters dated August 15, September 26, October 21, and November 24, 1986, and February 25, March 19, March 31, April 9, April 13, May 22, June 11, September 1, and December 11, 1987, March 2, and June 7, 1988 and September 28, 1990; (2) Amendment No. 104 to Facility Operating License No. DPR-28; (3) The Environmental Assessment dated July 29, 1988; (4) and the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the Brooks Memorial Library, 224 Main Street, Brattleboro, Vermont 05301. A copy of items (2), (3) and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects I/II.

Dated at Rockville, Maryland this 10th day of July 1991.

For the Nuclear Regulatory Commission.

Morton B. Fairtile,

Senior Project Manager, Project Directorate I-3, Division of Reactor Projects—I/II.

[FR Doc. 91-17358 Filed 7-19-91; 8:45 am]

BILLING CODE 7590-01-M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of Reporting Requirements Submitted for Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Comments should be submitted on or before August 21, 1991. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (S.F. 83), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Cleo Verbillis, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416, Telephone: (202) 205-6629.

OMB Reviewer: Gary Waxman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

Title: Certified Development Company Annual Report Guide.
Form No: SBA Forms 1253, 1253A.
Frequency: Annual.
Description of Respondents: Certified Development Companies.
Annual Responses: 410.
Annual Burden: 14,760.

Title: Survey of MED-Week Procurment Trade Fair Participants.
Form No: SBA Form 1808.
Frequency: Annual.
Description of Respondents: Small Business Exhibit Material at the MED-Week Procurement Trade Fair.
Annual Responses: 210.
Annual Burden: 10.5.

Cleo Verbillis,

Acting Chief, Administrative Information Branch.

[FR Doc. 91-17312 Filed 7-19-91; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2499; Amdt. No. 3]

Louisiana (With Contiguous Counties in Texas & Arkansas); Declaration of Disaster Loan Area

The above-numbered Declaration is hereby amended in accordance with amendments dated July 1 and 2, 1991, to the President's major disaster declaration of April 23, to include the parishes of Lafourche, Ouachita, and Terrebonne in the State of Louisiana as a disaster area as a result of damages caused by severe storms and flooding beginning on April 12 and continuing through April 26, 1991.

In addition, applications for economic injury loans from small businesses located in the contiguous parishes of Assumption, Evangeline, Jefferson, St. Charles, St. James, St. John the Baptist, and St. Mary in the State of Lousiana may be filed with until the specified date at the previously designated location.

As the termination date for filing applications for physical damage closed on June 22, 1991, prior to the Notices of Amendment cited above, the termination date for filing applications for physical damage for victims of the above-named parishes will be as follows: For Ouachita Parish, the deadline will be August 1, 1991; for the remaining primary and contiguous parishes the deadline will be July 31, 1990, 30 days from the respective amendments. The termination date for filing applications for economic injury remains the close of business January 23, 1992.

The economic injury numbers are 729900 for Louisiana, 730000 for Texas; and 730100 for Arkansas.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: July 3, 1991.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 91-17313 Filed 7-19-91; 8:45 am]

BILLING CODE 8025-01-M

[License No. 10/10-0180]

Alaska Business Investment Corp.; Notice of License Surrender

Notice is hereby given that Alaska Business Investment Corporation, 301 West Northern Lights Blvd., Anchorage, Alaska 99510, has surrendered its license to operate as a small business investment company under section 301(c) of the Small Business Investment Act of 1958, as amended (the Act). Alaska Business Investment Corporation was licensed by the Small Business Administration on December 10, 1982.

Under the authority vested by the Act and pursuant to the regulations promulgated thereunder, the surrender of the license was accepted on July 10, 1991 and accordingly, all rights,

privileges and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: July 12, 1991.

Bernard Kulik,

Associate Administrator for Investment.

[FR Doc. 91-17314 Filed 7-19-91; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

National Offshore Safety Advisory Committee

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. I), notice hereby is given of a meeting of the National Offshore Safety Advisory Committee (NOSAC). The meeting will be held on Wednesday, August 21, 1991, in room 2317, at the McDermott Offices, 1010 Common Street, New Orleans, Louisiana (504) 587-4411. The meeting is scheduled to run from 9 a.m. to 12 noon. Attendance is open to the public. The agenda follows:

1. Subcommittee Reports
   (a) Subchapter W
   (b) Vessel Tonnage
   (c) MODU Code Revision
   (d) Drug Testing
   (e) Ocean Tow of Jack-up Drilling Units
   (f) Revisions to Regulations on Outer Continental Shelf Activities
   (g) Future Inspection Regulations for Crewboats
   (h) Clean Air Act Amendments of 1990
2. Other Issues to be Discussed

With advance notice, and at the discretion of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present oral statements should notify the NOSAC Executive Director no later than the day before the meeting. Written statements or materials may be submitted for presentation to the Committee at any time; however, to ensure distribution to each Committee member, 20 copies of the written materials should be submitted to the Executive Director no later than August 10, 1991.

FOR FURTHER INFORMATION CONTACT: Ms. Jo Pensivy, Executive Director, National Offshore Safety Advisory Committee (NOSAC), room 2414, U.S. Coast Guard Headquarters, 2100 Second St., SW., Washington, DC 20593-0001. (202) 267-1406.

Dated: July 12, 1991

D.H. Whitten,

Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 91-17320 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-14-M

[CGD 91-010]

Oil Pollution Act of 1990—Designating Areas For Area Committees

AGENCY: Coast Guard, DOT.

ACTION: Notice of intent.

SUMMARY: The Coast Guard is providing advance notice of how it will designate some of the areas for which Area Committees are required to conduct regional oil spill contingency planning under the Oil Pollution Act of 1990. Other areas will be designated by the Environmental Protection Agency in a separate notice. This division of responsibility reflects the working arrangements between the two agencies under existing national and regional oil spill contingency planning. Early notice will permit planning to begin. The Coast Guard will publish a notice designating the areas when the authority to do so is delegated to the Coast Guard.

FOR FURTHER INFORMATION CONTACT: Robert M. Gauvin, Project Manager, Oil Pollution Act Staff, Department of Transportation, U.S. Coast Guard, 2100 Second St., SW., Washington, DC 20593-0001, (202) 267-6226.

SUPPLEMENTARY INFORMATION: The Oil Pollution Act of 1990 (Pub. L. 101-380) (OPA 90) was enacted to reduce oil spills and to improve the nation's preparedness and ability to respond to them. OPA 90 creates a comprehensive prevention, response, liability, and compensation regime for dealing with vessel and facility-generated oil pollution.

Subtitle B of title IV of OPA 90 amends section 311 of the Federal Water Pollution Control Act (33 U.S.C. 1321)(FWPCA) and contains certain stand alone provisions to set out the requirements for enhanced response systems to clean up oil spills. In particular, section 4202(a) of OPA 90 amends section 311(j) of the FWPCA to describe how groups, called Area Committees, will participate in the contingency planning process and produce Area Contingency Plans (ACPs). Each ACP must include worst case scenarios and lists of equipment and personnel that are available for the removal of worst case spills. In case of an oil spill, an ACP would be implemented in conjunction with a national level plan which will be part of an amended National Contingency Plan (NCP) to be developed under section 311(d) of the FWPCA, as amended by section 4201 of OPA 90.

Section 4202(b) of OPA 90 directs the President to designate the areas for which Area Committees (whose members are also to be designated by the President) are to prepare ACPs under amended section 311(j)(4) of the FWPCA. Each Area Committee is to submit an ACP to the President by February 18, 1992, for approval.

At this time, the President has not delegated his authority under section 4202(b). An Executive Order (E.O.) to delegate the President's many responsibilities under OPA 90 to appropriate executive agencies is under development.

Under the E.O., the authority of the President to designate areas for the "coastal zone" is expected to be delegated to the Secretary of Transportation. The term "coastal zone," as defined in the current NCP at 40 CFR 300.5, means all United States waters subject to the tide, United States waters of the Great Lakes, specified ports and harbors on inland rivers, and the waters of the Exclusive Economic Zone (EEZ). In order for work on the required ACPs to commence in a timely manner, the Coast Guard is providing this advance notice of how it will designate areas under section 4202(b).

In addition, under the E.O., the authority to designate areas for the "inland zone," also defined in the NCP, is expected to be delegated to the Administrator of the Environmental Protection Agency (EPA). Accordingly, a separate notice to designate areas for the "inland zone" will be issued by the EPA.

The existing NCP divides the United States, its territories, and its possessions, into 13 areas of responsibility, including portions of the high seas. Each of the 13 areas of responsibility is divided further into coastal and inland zones. These areas correspond to the 10 standard Federal regions with the exception of the separate areas established for (1) Puerto Rico and the U.S. Virgin Islands of Region II; (2) Alaska of Region X; and (3) Hawaii, Guam, Northern Mariana Islands, Pacific Island Governments, and American Samoa of Region IX. Each of these areas is covered by its own Regional Response Team (RRT) and Regional Contingency Plan (RCP).

The Coast Guard divides the United States, its territories, and its possessions into 47 Captain of the Port (COTP) zones

which cover all of the United States, including portions of the high seas. Each COTP zone is described in the Coast Guard regulations at 33 CFR Part 3. COTPs and their representatives enforce, within their respective zones, port safety, security, and marine environmental protection regulations. Each Coast Guard COTP is also the predesignated Federal On-Scene Coordinator (FOSC) under the NCP for the coastal portion of a COTP zone.

The Coast Guard will designate as areas, for which Area Committees will prepare ACPs, those portions of the COTP zones which are within the coastal zone. Since the term "area" has a different, and specific, Coast Guard meaning, each area will be called a "Port Area."

The specific Port Area boundaries are not listed in this notice. The boundaries for inland and coastal zones have been defined clearly by the Coast Guard COTPs and the EPA Regional Administrators through Memoranda-of-Understanding. The precise boundaries are described in the RCPs published for each of the 13 areas of responsibility under the NCP. The boundaries also are found in the current local contingency plan for each COTP. RCPs are available for viewing at the Coast Guard District and COTP Offices listed in Table I. COTP local contingency plans within each Coast Guard District are available for viewing at each District Office and at respective COTP Offices.

To address significant local requirements or concerns, the Coast Guard intends to delegate to each COTP the authority to divide further a Port Area. If a Port Area is divided, each portion then will constitute a separate Port Area for which a separate Area Committee will prepare and submit a separate ACP. Some Port Areas may be divided during the initial implementation of the contingency planning requirements of OPA 90, while some Port Areas may be divided at a later date.

By using COTP zones as a basis for defining Port Areas, the Coast Guard will meet the requirement of section 4202(b)(1) of OPA 90 that, within the coastal zone, all navigable waters, adjoining shorelines, and waters of the EEZ will be subject to an ACP.

The Coast Guard will publish a notice formally designating the Port Areas after the E.O. has been issued and the authority has been redelegated to the Coast Guard by the Secretary of Transportation.

The Coast Guard encourages representatives of State and local government agencies and interested members of the public to contact the Port Operations Department at COTP Offices for further information concerning OPA 90, including Port Area boundaries. The addresses and telephone numbers for COTP Offices are listed in Table I.

Dated: June 26, 1991.

A.E. Henn,

Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Safety, Security and Environmental Protection.

Table I—*U.S. Coast Guard District and Captain of the Port Offices*

Commander
First Coast Guard District
Coast Guard Bldg.
408 Atlantic Ave.
Boston, MA 02210–2209
617/223–8480

Commanding Officer, Marine Safety Office Portland, 76 Pearl St., Portland, ME 04112–0196, 207/780–3251	Commanding Officer, Marine Safety Office Boston, 455 Commercial Street, Boston, MA 02109–1045, 617/565–3025.
Commanding Officer, Marine Safety Office Providence, John O'Pastore Federal Building, Providence, RI 02903–1790, 401/528–5335	Captain of the Port New York, c/o USCG Group, Governors Island, New York, NY 10004–5000, 212/668–7917.
Captain of the Port Long Island Sound, c/o USCG Group, 120 Woodward Ave., New Haven, CT 06512–3698, 203/468–4464	

Commander
Second Coast Guard District
1430 Olive Street
St. Louis, MO 63103–2398
314/425–4601

Commanding Officer, Marine Safety Office St. Louis, Suite 1.215, 1222 Spruce St., St. Louis, MO 63103–2835, 314/539–3091	Commanding Officer, Marine Safety Office Huntington, 1415 6th Ave., Huntington, WV 25701–2420, 304/529–5524.
Commanding Officer, Marine Safety Office Louisville, Room 360, 600 Martin Luther King Jr. Place, Louisville, KY 40202–2230, 502/582–5194	Commanding Officer, Marine Safety Office Memphis, Suite 1301, 200 Jefferson Ave., Memphis, TN 38103–2300, 901/521–3941.
Commanding Officer, Marine Safety Office Paducah, P.O. Box 7509, 200 Katterjohn Bldg., 1501 Broadway, Paducah, KY 42002–7509, 502/442–1621	Commanding Officer, Marine Safety Office Pittsburgh, Suite 700, Kossman Bldg., Forbes Ave. & Stanwix St., Pittsburgh, PA 15222–1371, 412/644–5808.

Table I—*U.S. Coast Guard District and Captain of the Port Offices*—Continued

Commander
Fifth Coast Guard District
Federal Bldg.
431 Crawford St.
Portsmouth, VA 23704–5004
804/398–9638

Commanding Officer, Marine Safety Office Baltimore, Customhouse, 40 S. Gay St., Baltimore, MD 21202–4022, 301/962–5105	Commanding Officer, Marine Safety Office Hampton Roads, Norfolk Federal Bldg., 200 Granby St., Norfolk, VA 23510–1888, 804/441–3299.
Commanding Officer, Marine Safety Office Philadelphia, 1 Washington Ave., Philadelphia, PA 19147–4395, 215/271–4803	Commanding Officer, Marine Safety Office Wilmington, Suite 500, 272 N. Front St., Wilmington, NC 28401–3907, 919/343–4892.

Commander
Seventh Coast Guard district
Brickell Plaza Bldg.
909 S.E. 1st Ave.
Miami, FL 33131–3050
305/536–5654

Commanding Officer, Marine Safety Office Miami, 155 S. Miami Ave., Miami, FL 33130–1609, 305/536–5693	Commanding Officer, Marine Safety Office Jacksonville, Room 213, 2131 Talleyrand Ave., Jacksonville, FL, 32206–3497, 904/791–2648.
Commanding Officer, Marine Safety Office Tampa, 155 Columbia Dr., Tampa, FL 33606–3598, 813/228–2194	Commanding Officer, Marine Safety Office Savannah, P.O. Box 8191, Savannah, GA 31412–8191, 912/944–4371.
Commanding Officer, Marine Safety Office Charleston, 196 Tradd St., Charleston, SC 29401–1899, 803/724–8689	Commanding Officer, Marine Safety Office San Juan, USCG Base La Puntilla, Old San Juan, PR, 00902–3666, 809/944–2697.

Commander
Eighth Coast Guard District
Hale Boggs Federal Bldg., Rm 1331
501 Magazine St.
New Orleans, LA 70130–3396
504/589–6901

Commanding Officer, Marine Safety Office New Orleans, Tidewater Bldg., 1440 Canal Street, New Orleans, LA 70112–2711, 504/589–4256	Commanding Officer Marine Safety Office Morgan City, Rm 232, 800 David Dr., Morgan City, LA, 70380–1304, 504/384–2406.

Table I—*U.S. Coast Guard District and Captain of the Port Offices*—Continued

Commanding Officer, Marine Safety Office Corpus Christi, P.O. Box 1621, Corpus Christi, TX 78403-1621, 512/888-3162	Commanding Officer, Marine Safety Office Galveston, Post Office Bldg., Rm. 313, 601 Rosenberg, Galveston, TX 77550-1705, 409/766-3678.
Commanding Officer, Marine Safety Office Houston, P.O. Box 446, Galena Park, TX 77547-0446, 713/671-5122	Commanding Officer, Marine Safety Office Mobile, 150 N. Royal St., Mobile, AL 36652-2924, 205/690-2286.
Commanding Officer, Marine Safety Office Port Arthur, Federal Bldg., 2875 75th St. & Hwy 69, Port Arthur, TX 77640-2099, 409/723-6506	

Commander
Ninth Coast Guard District
1240 E. 9th Street
Clevelend, OH 44199-2060
216/522-3994

Commanding Officer, Marine Safety Office Buffalo, Rm 1111, Federal Bldg., 111 West Huron St., Buffalo, NY 14202-2395, 716/846-4168	Commanding Officer, Marine Safety Office Chicago, 610 S. Canal St., Chicago, IL 60607-4573, 312/353-3627.
Commanding Officer, Marine Safety Office Cleveland, 1055 East 9th St., Cleveland, OH 44114-1092, 216/522-4405	Commanding Officer, Marine Safety Office Detroit, Ft. of Mt. Elliot Ave., Detroit, MI 48207-4380, 568/374-9488.
Commanding Officer, Marine Safety Office Duluth, Canal Park, Duluth, MI 55802-2352, 218/720-5288	Captain of the Port Grand Haven, c/o USCG Group, 650 Harbor Ave., Grand Haven, MI 49417, 616/847-4504.
Commanding Officer, Marine Safety Office Milwaukee, 2420 S. Lincoln Memorial Dr., Milwaukee, WI 53207-1997, 414/370-7159	Captain of the Port Sault Ste. Marie, c/o USCG Group, Sault Ste. Marie, MI, 49783-9501, 906/372-3210.
Commanding Officer, Marine Safety Office Toledo, Rm. 501, Federal Bldg., 234 Summit St., Toledo, OH 43604-1590, 419/259-6372	

Commander
Eleventh Coast Guard District
400 Oceangate
Long Beach, CA 90822-5399
213/499-5330

Table I—*U.S. Coast Guard District and Captain of the Port Offices*—Continued

Commanding Officer, Marine Safety Office Long Beach, Los Angeles/Long Beach, 165 N. Pico Ave., Long Beach, CA 90802-1096, 213/499-5573	Commanding Officer, Marine Safety Office San Diego, 2710 N. Harbor Dr., San Diego, CA 92101-1064, 619/557-5877.
Commanding Officer, Marine Safety Office San Francisco, Bldg. 14, Coast Guard Island, Alameda, CA 94501-5100, 415/437-3082	

Commander
Thirteenth Coast Guard District
Jackson Federal Bldg.
915 Second Ave.
Seattle, WA 98174-1067
206/442-5233

Commanding Officer, Marine Safety Office Portland, 6767 N. Basin Avenue, Portland, OR 97217-3929, 503/240-9324	Commanding Officer, Marine Safety Office Puget Sound, Bldg. 1/Pier 36, 1519 Alaskan Way S. Seattle, WA 98134-1192, 206/286-5530.

Commander
Fourteenth Coast Guard District
9th floor, Room 9153
Prince Kalanianaole Federal Bldg.
300 Ala Moana Blvd.
Honolulu, HI 98650-4982
808/541-2114

Commanding Officer, Marine Safety Office Honolulu, Rm. 1, 433 Ala Moana Blvd., Honolulu, HI 96813-4909, 808/541-2068	Commanding Officer, Marine Safety Office Guam, Box 176, FPO San Francisco, CA, 96630-5000, 550-7314.

Commander
Seventeenth Coast Guard District
P.O. Box 3-5000
Juneau, AK 99802-1217
907/586-7197

Commanding Officer, Marine Safety Office Juneau, Suite 2A, 2760 Sherwood Ln., Juneau, AK 99801-8545, 907/586-7288	Commanding Officer, Marine Safety Office Anchorage, Federal Bldg. &, U.S. Courthouse, Box 17, 701 C St., Anchorage, AK 99513-0065, 907/271-5137.
Commanding Officer, Marine Safety Office Valdez, P.O. Box 486, Valdez, AK 99686-0486, 907/835-4791	

[FR Doc. 91-17321 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-14-M

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Rotorcraft Subcommittee.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of establishment of Rotorcraft Subcommittee.

SUMMARY: Notice is given of the establishment of Rotorcraft Subcommittee of the FAA Aviation Rulemaking Advisory Committee. This notice informs the public of the activities of the Aviation Rulemaking Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Mr. William J. (Joe) Sullivan, Executive Director, Rotorcraft Subcommittee, Aircraft Certification Service (AIR-3), 800 Independence Avenue SW., Washington, DC 20591, Telephone: (202) 267-9554; FAX: (202) 267-9562.

SUPPLEMENTARY INFORMATION: On January 14, 1991, the Federal Aviation Administration (FAA) announced the establishment of the Aviation Rulemaking Advisory Committee (56 FR 2190, January 22, 1991). The committee charter became effective on February 5, 1991, when notices of establishment were sent to the appropriate Congressional Committees. The advisory committee provides advice and recommendations to the FAA concerning the full range of the FAA's rulemaking activity with respect to safety-related issues, including aircraft certification. The committee held its first meeting at Baltimore, MD, on May 23, 1991 (56 FR 20492, May 3, 1991). At that meeting, the committee formed several subcommittees and charged them with developing advisory recommendations in different safety-related areas. The subcommittee Chairs and Executive Directors were named, and the member organizations identified.

Finally, several specific tasks were assigned to the various subcommittees. At this first meeting, the committee also adopted procedures concerning the operation of the committee, its subcommittees, and their working groups.

Under the procedures adopted by the full committee, each subcommittee meeting is open to the public, except as authorized in section 10(d) of the Federal Advisory Committee Act. Also, notice is given beforehand of the subcommittee meeting agenda. A subcommittee may form working groups made up of experts from those having an interest in an issue to do tasks assigned to the subcommittee. Working group

meetings need not be open to the public. This is because working groups must bring their work product back to the subcommittee for full, open, and substantive discussion, and may not communicate directly with the FAA. The subcommittee may: (1) Accept a working group work product and send it directly to the FAA; (2) Modify the work product and send it directly to the FAA; or (3) Return the work product to the working group with instructions for further activity. Thus, while the functions of a subcommittee are solely advisory, they create a framework within which interested parties may negotiate proposed or final rules and present their consensus to the FAA for action. The more complete these products, the more likely they are to be accepted by the FAA without change and formally published as proposed or final rules. The activities of the Aviation Rulemaking Advisory Committee, and its subcommittees, are consistent with the newly enacted Negotiated Rulemaking Act of 1990 (Pub. L. 101-648).

The Rotorcraft Subcommittee will provide advice and recommendations to the Director, Aircraft Certification Service, FAA, regarding the airworthiness standards for normal and transport category rotorcraft in parts 27 and 29 of the Federal Aviation Regulations. The membership of the Rotorcraft Subcommittee consists solely of the following members of the Aviation Rulemaking Advisory Committee:

- Aerospace Industries Association
- Aircraft Electronics Association
- Aircraft Owners and Pilots Association
- Airline Passengers Association of North America
- Alaska Air Carrier Association
- Association Europenne des Constructeurs de Material Aerospatiale
- Experimental Aircraft Association
- Flight Safety Foundation
- Helicopter Association International
- Joint Aviation Authorities
- McDonnell Douglas Corporation
- National Agricultural Aviation Association
- National Business Aircraft Association

The date, place, and agenda for the first meeting of Rotorcraft Subcommittee meeting is announced elsewhere in this issue of the Federal Register. The Secretary of Transportation has determined that the formation and use of the Aviation Rulemaking Advisory Committee and its subcommittees are necessary in the public interest in connection with the performance of duties imposed on the FAA by law.

Issued in Washington, DC, on July 15, 1991.

William J. Sullivan,

Executive Director, Transport Airplane and Engine Subcommittee, Aviation Rulemaking Advisory Committee.

[FR Doc. 91-17333 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

Rotorcraft Subcommittee of the Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration Rotorcraft Subcommittee of the Aviation Rulemaking Advisory Committee.

DATES: The meeting will be held on September 25, 1991, at 9 a.m. Arrange for oral presentations by September 13, 1991.

ADDRESSES: The meeting will be held in the Conference Room, Helicopter Association International, 3d floor, 1619 Duke Street, Alexandria, VA 22314-3406.

FOR FURTHER INFORMATION CONTACT: Ms. Marge Ross, Aircraft Certification Service (AIR-1), 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267-8235.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Rotorcraft Subcommittee to be held on September 25, 1991, in the Conference Room, Helicopter Association International, 3d floor, 1619 Duke Street, Alexandria, VA 22314-3406. The agenda for this meeting will include a briefing from the staff of the FAA Aircraft Certification Rotorcraft Directorate on the Directorate's rulemaking program, international harmonization activities, and the relevant priorities for this programs. The subcommittee will then develop recommendations to the Director, Aircraft Certification Service, as to the working groups the Rotorcraft Subcommittee should be asked to form, and the tasks to assign to each working group.

Attendance is open to the interested public, but will be limited to the space available. The public must make arrangements by September 13, 1991, to present oral statements at the meeting. The public may present written statements to the committee at any time by providing 16 copies to the Executive Director, or by bringing the copies to him at the meeting. Arrangements may be made by contacting the person listed under the heading **"FOR FURTHER INFORMATION CONTACT."**

Issued in Washington, DC, on July 15, 1991.

William J. Sullivan,

Executive Director Transport Airplane and Engine Subcommittee, Aviation Rulemaking Advisory Committee.

[FR Doc. 91-17332 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

July 15, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: New.
Form Number: IRS Form 8829.
Type of Review: New collection.
Title: Expenses for Businesses Use of Your Home.
Description: Internal Revenue Code (IRC) section 280A limits the deduction for business use of a home to the gross income from the businesses use minus certain business deductions. Amounts not allowed due to the limitations can be carried over to the following year. Form 8829 is used to verify that the deduction is properly figured.
Respondents: Individuals or households.
Estimated Number of Respondents/ Recordkeepers: 4,000,000.
Estimated Burden Hours Per Respondent/Recordkeeper:
Recordkeeping—52 minutes
Learning about the law or the form—7 minutes
Preparing the form—1 hr., 10 minutes
Copying, assembling, and sending the form to IRS—20 minutes
Frequency of Response: Annually.
Estimated Total Reporting/ Recordkeeping Burden: 10,200,000 hours.

OMB Number: 1545–0059.
Form Number: IRS Form 4137.
Type of Review: Revision.
Title: Social Security and Medicare Tax on Unreported Tip Income.
Description: Internal Revenue Code (IRC) section 3102 requires an employee who receives tips subject to ICA tax to compute tax due on these tips if the employee did not report them to his or her employer. The data is used to help verify the FICA tax on tip income is correctly computed.
Respondents: Individuals or households.
Estimated Number of Respondents/ Recordkeepers: 76,000.
Estimated Burden Hours Per Respondent/Recordkeeper:
Recordkeeping—26 minutes
Learning about the law or the form—5 minutes
Preparing the form—16 minutes
Copying, assembling, and sending the form to IRS—17 minutes
Frequency of Response: Annually.
Estimated Total Reporting/ Recordkeeping Burden: 92,720 hours.
OMB Number: 1545–0085.
Form Number: IRS Form 1040A, Schedules 1, 2, 3, and 4.
Type of Review: Revision.
Title: U.S. Individual Income Tax Return.
Description: This form is used by individuals to report their income subject to income tax and to compute their correct tax liability. The data is used to verify that the income reported on the form are correct and are also for statistics use.
Respondents: Individuals or households.
Estimated Number of Respondents/ Recordkeepers: 21,106,380.

Estimated Burden Hours Per Respondent/Recordkeeper:

	Recordkeeping	Learning about the law or the form	Preparing the form	Copying, assembling, and sending the form to IRS
1040A	1 hr., 3 min	2 hrs., 15 min	2 hrs., 55 min	35 min.
Sched. 1	20 min	4 min	10 min	20 min.
Sched. 2	33 min	11 min	37 min	28 min.
Sched. 3	13 min	14 min	26 min	35 min.
Sched. 4	40 min	17 min	34 min	48 min.

Frequency of Response: Annually.
Estimated Total Reporting/ Recordkeeping Burden: 166,750,875 hours.
Clearance Officer: Garrick Shear, (202) 535–4297, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 91–17309 Filed 7–18–91; 8:45 am]
BILLING CODE 4830–01–M

[General Counsel Designation No. 179]

Appointment of Members of the Legal Division to the Performance Review Board

Under the authority granted to me as Acting General Counsel of the Department of the Treasury by 31 U.S.C. 301 and 26 U.S.C. 7801, Treasury Department Order No. 101–5 (Revised), and pursuant to the Civil Service Reform Act, I hereby appoint the following persons to the Legal Division Performance Review Board:

(1) For the General Counsel Panel—
Dennis I. Foreman, Deputy General Counsel, who shall serve as Chairperson;
Russell L. Munk, Assistant General Counsel (International Affairs);
Kenneth R. Schmalzbach, Assistant General Counsel (Administrative & General Law)
Robert M. McNamara, Jr., Assistant General Counsel (Enforcement)
Marvin J. Dessler, Chief Counsel, Bureau of Alcohol, Tobacco, and Firearms; and
Michael T. Schmitz, Chief Counsel, United States Customs Service.
(2) For the Internal Revenue Service Panel—
Chairperson, Deputy Chief Counsel, IRS; Deputy General Counsel; Two Associate Chief Counsel, IRS; and Two Regional Counsel, IRS.

I hereby delegate to the Chief Counsel of the Internal Revenue Service the authority to make the appointments to the IRS Panel specified in this Designation and to make the publication of the IRS Panel as required by 5 U.S.C. 4314(c)(4).

Dated: July 16, 1991.
Jeanne S. Archibald,
General Counsel.
[FR Doc. 91–17310 Filed 7–18–91; 8:45 am]
BILLING CODE 4810–25–M

Office of Thrift Supervision

Atlantic Permanent Federal Savings Bank, Norfolk, VA; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Atlantic Permanent Federal Savings Bank, Norfolk, Virginia ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 12, 1991.

Dated: July 16, 1991.
By the Office of Thrift Supervision.
Nadine Y. Washington,
Corporate Secretary.
[FR Doc. 91–17336 Filed 7–19–91; 8:45 am]
BILLING CODE 6720–01–M

Citizens & Builders Federal Savings, F.S.B., Pensacola, FL; Replacement of Conservator With a Receiver

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owners' Loan Act, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Citizens & Builders Federal Savings, F.S.B., Pensacola, Florida ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on July 12, 1991.

Dated: July 16, 1991.
By the Office of Thrift Supervision.
Nadine Y. Washington,
Corporate Secretary.
[FR Doc. 91–17335 Filed 7–19–91; 8:45 am]
BILLING CODE 6720–01–M

Sunshine Act Meetings

Federal Register
Vol. 54, No. 140
Monday, July 22, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

U.S. CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10:00 a.m., Wednesday, July 24, 1991.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Open to the Public.

MATTERS TO BE CONSIDERED: FY 93 Budget.

The Commission will consider the budget for fiscal year 1993.

For a Recorded Message Containing the Latest Agenda Information, Call (301) 492–5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, MD 20207 (301) 492–6800.

Dated: July 18, 1991.

Sheldon D. Butts,

Deputy Secretary.

[FR Doc. 91–17442 Filed 7–18–91; 1:24 pm]

BILLING CODE 6355–01–M

U.S. CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 2:00 p.m., Thursday, July 25, 1991.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Closed to Public.

MATTERS TO BE CONSIDERED: Compliance Status Report.

The staff will brief the Commission on the status of various compliance matters.

For a Recorded Message Containing the Latest Agenda Information, Call (301) 492–5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 (301) 492–6800.

Dated: July 18, 1991.

Sheldon D. Butts,

Deputy Secretary.

[FR Doc. 91–17443 Filed 7–18–91; 1:24 pm]

BILLING CODE 6355–01–M

RESOLUTION TRUST CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:40 p.m. on Tuesday, July 16, 1991, the Board of Directors of the Resolution Trust Corporation met in closed session to consider matters relating to the resolution of failed thrift institutions.

In calling the meeting, the Board determined, on motion of Director T. Timothy Ryan Jr. (Director of Office of Thrift Supervision), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Chairman L. William Seidman, Vice Chairman Andrew C. Hove, Jr., and Director C.C. Hope (Appointive), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b).

The meeting was held in the Board Room of the Federal Deposit Insurance Corporation Building located at 550–17th Street NW., Washington, DC.

Dated: July 17, 1991.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Executive Secretary.

[FR Doc. 91–17410 Filed 7–17–91; 4:50 pm]

BILLING CODE 6714–01–M

Corrections

Federal Register
Vol. 56, No. 140
Monday, July 22, 1991

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 5, 8, 9, 10, 14, 15, 16, 17, 19, 25, 27, 31, 35, 36, 42, 43, 44, 45, 49, and 52

RIN 9000-AC43, 9000-AE12, 9000-AD85, 9000-AE00, 9000-AD32, 9000-AE01, 9000-AD66, 9000-AD21, 9000-AD57, 9000-AD08, 9000-AE05, 9000-AD73, 9000-AD02, 9000-AD78, 9000-AD81, 9000-AD77, 9000-AD33

[FAC 90-4]

Federal Acquisition Regulation (FAR); Miscellaneous Amendments

Correction

In rule document 91-8647 beginning on page 15142, in the issue of Monday, April 15, 1991, make the following corrections:

1. On page 15146, in the first column, in the 14th line, "Robert H. Hope" should read "Robert H. Hopf".

§ 25.703 [Corrected]

2. On page 15152, in the 2nd column, in § 25.703(a), in the 10th line remove "not".

§ 52.214-34 [Corrected]

3. On page 15155, in the 1st column, the section number in the heading following amendatory instruction 54 should read as shown above.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

[Program Announcement Number 141]

Identification and Prevention of Air Pollutants and Other Environmental Determinants of Asthma Among Minority Children in Urban Areas; Availability of Fund for Fiscal Year 1991

Correction

In notice document 91-15334 beginning on page 29488 in the issue of Thursday, June 27, 1991, make the following corrections:

1. On page 29488, in the 2d column, under **ELIGIBLE APPLICANTS**, in the 1st paragraph, in the 2d line, "of" should read "or"; and in the 11th line, "organization" should read "organizational".

2. On the same page, in the same column, under the same heading, in the third paragraph, in the seventh line from the bottom, "to" should read "be".

3. On page 29489, in the first column, under **EVALUATION CRITERIA**, in the third paragraph *(B. Understanding ***)*, in the last line, "for" should read "of".

4. On the same page, in the second column, in the fifth line from the bottom of the page, "01/89" should read "03/89".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[FI-139-86]

RIN 1545-AJ51

Discounted Unpaid Losses

Correction

In proposed rule document 91-10320 beginning on page 20161, in the issue of Thursday, May 2, 1991 make the following correction:

§ 1.846-1 [Corrected]

1. On page 20163, in the second column, in § 1.846-1(b)(1)(ii), in the fifth line "those" should read "composite".

BILLING CODE 1505-01-D

federal register

Monday
July 22, 1991

Part II

Environmental Protection Agency

40 CFR Parts 60 et al.

Hazardous Waste Treatment, Storage, and Disposal Facilities; Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 260, 264, 265, 270, and 271

[AD-FRL-3611-4]

RIN 2060-AB94

Hazardous Waste Treatment, Storage, and Disposal Facilities; Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is today proposing new standards and amendments to existing standards that would further reduce air emissions from hazardous waste management units subject to regulation under the Resource Conservation and Recovery Act (RCRA) as amended. New standards are proposed for hazardous waste treatment, storage, and disposal facilities (TSDF) subject to permitting requirements under RCRA subtitle C that would require organic emission controls be installed and operated on tanks, surface impoundments, containers, and certain miscellaneous units if any hazardous waste having a volatile organic concentration equal to or greater than 500 parts per million by weight (ppmw) is placed in the unit. In addition, EPA is proposing amendments that would add the relevant emission control requirements specified by the air emission standards under RCRA for certain TSDF treatment unit process vents (40 CFR 265 subpart AA), TSDF equipment leaks (40 CFR 265 subpart BB), and TSDF tanks, surface impoundments, and containers (proposed today as 40 CFR 265 subpart CC) to the requirements that a hazardous waste generator must comply with pursuant to 40 CFR 262.34(a) in order to exempt certain accumulation tanks and containers from the RCRA subtitle C permitting requirements. Also, EPA is proposing an amendment to 40 CFR 270.4 that would require the owner or operator of a TSDF already issued a permit under RCRA subtitle C to comply with the air emission standards for interim status facilities (40 CFR part 265) until the facility's permit is reviewed or reissued by EPA.

Today's action is proposed under the authority of RCRA sections 3002 and 3004, and is the second phase of a three-phased regulatory program to control air emissions from the treatment, storage, and disposal of hazardous waste. The first phase was completed with the promulgation of final standards controlling organic emissions from certain TSDF treatment unit process vents and TSDF equipment leaks (55 FR 25454, June 21, 1990). For the third phase, EPA will assess the residual risk that remains after implementation of the standards developed in the first two phases and, if necessary, will develop additional standards or guidance to protect human health and the environment from TSDF air emissions.

DATES: *Comments.* The EPA will accept comments from the public on the proposed standards until September 20, 1991. If requested, a public hearing will be held on this proposed rulemaking to provide interested parties an opportunity for oral presentations of data or views concerning the proposed standards. See section XI of this preamble for the schedule and location of this public hearing.

ADDRESSES: *Background Information Document.* The background information document (BID) for the proposed standards may be obtained from U.S. EPA Library (MD-35), Research Triangle Park, North Carolina 27711, telephone (919) 541-2777. Please refer to "Hazardous Waste TSDF—Background Information for Proposed RCRA Air Emission Standards" (EPA-450/3-89-23).

Docket. The official record for the proposed standards is contained in Docket No. F-91-CESP-FFFFF. This docket is available for public inspection between the hours of 8 a.m. and 4 p.m., Monday through Friday, excluding legal holidays, at the EPA RCRA Docket Office (OS-305), room 2427, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

Comments. Written comments regarding the proposed standards may be mailed to the Docket Clerk (OS-305), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Please refer to Docket Number F-91-CESP-FFFFF, Air Emission Standards for Organics Control.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline, toll free at (800) 424-9346, or at (202) 382-3000, or the following EPA staff. For information concerning regulatory aspects, contact Ms. Gail Lacy, Standards Development Branch, Emission Standards Division (MD-13), U.S. EPA, Research Triangle Park, NC 27711, telephone (919) 541-5261. For information concerning technical aspects, contact Ms. Michele Aston, Chemicals and Petroleum Branch, Emission Standards Division (MD-13), U.S. EPA Research Triangle Park, NC 27711, telephone (919) 541-2363. For information concerning the test methods, contact Mr. Terry Harrison, Emission Measurement Branch, Technical Support Division (MD-14), U.S. EPA, Research Triangle Park, NC 27711, telephone (919) 541-5233.

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

I. SUMMARY OF TODAY'S PROPOSAL

The EPA is proposing today new standards and amendments to existing standards that would further reduce air emissions from hazardous waste management units subject to regulation under the Resource Conservation and Recovery Act (RCRA) as amended by the Hazardous and Solid Waste Amendments (HSWA). Specifically, EPA is proposing:

(a) New standards, subpart CC, to be added to 40 CFR parts 264 and 265 that would require owners and operators of hazardous waste treatment, storage, and disposal facilities (TSDF) subject to the RCRA subtitle C permitting requirements to install and operate organic emission controls on certain tanks, surface impoundments, and containers.

(b) Two new test methods to be added to both 40 CFR part 60 Appendix A—"Standards of Performance for New Stationary Sources Reference Methods" and EPA Publication No. SW-846, "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," that would be used for determining the volatile organic content and vapor-phase organic concentration in waste samples.

(c) An amendment to 40 CFR 264.601 that would require the permit terms and provisions for a miscellaneous unit being permitted under 40 CFR 264 subpart X to include the appropriate emission control requirements specified by the air emission standards for certain TSDF treatment unit process vents (40 CFR 264 subpart AA), TSDF equipment leaks (40 CFR 264 subpart BB), and TSDF tanks, surface impoundments, and containers (proposed today as 40 CFR 264 subpart CC).

(d) An amendment to 40 CFR 270.4 that would require the owner or operator of a TSDF already issued a permit under RCRA subtitle C to comply with the air emission standards for interim status facilities (40 CFR part 265) until the facility's permit is reviewed or is reissued by EPA.

(e) Amendments to 40 CFR 265 subparts I and J that would add the relevant emission control requirements specified by the air emission standards for certain TSDF treatment unit process vents (40 CFR part 265 subpart AA), TSDF equipment leaks (40 CFR 265 subpart BB), and TSDF tanks, surface impoundments, and containers (proposed today as 40 CFR 265 subpart CC) to the requirements that a hazardous waste generator must comply with pursuant to 40 CFR 262.34(a) in order to exempt tanks and containers accumulating waste on-site for no more than 90 days from the RCRA subtitle C permitting requirements. The EPA may implement these requirements for hazardous waste generators as HSWA requirements; thereby making the standards applicable to generators as Federal law.

(f) Amendments to 40 CFR 264 subparts AA and BB and to 40 CFR part 265 subparts AA and BB that would require owners and operators using carbon adsorption systems to comply with the standards to certify that the spent carbon removed from the system is either: (1) Regenerated or reactivated by a process that minimizes the release of organics to the atmosphere by using effective control devices such as those now required by 40 CFR part 264 subpart AA, or (2) incinerated in a thermal treatment device that complies with the requirements of 40 CFR part 264 subpart O. The same provision is included in the standards proposed today as subpart CC to 40 CFR parts 264 and 265.

A. Proposed TSDF Tank, Surface Impoundment, and Container Standards

1. Need for Standards

Nationwide organic emissions from TSDF are estimated to be approximately 1.8 million megagrams per year (Mg/yr) (2,000,000 tons per year). These organic emissions can contain toxic chemical compounds as well as ozone precursors. Cancer and other adverse noncancer human health effects can result from exposure to these organic emissions. The nationwide TSDF organic emissions are estimated to result in 140 excess incidences of cancer per year nationwide and a 2×10^{-2} maximum lifetime individual risk of cancer. In addition, these emissions contribute to formation of ozone which causes adverse impacts on human health (e.g., lung damage) and the environment (e.g., reduction in crop yields). Excessive ambient ozone concentrations are a major air quality problem in many large cities throughout the United States.

In 1984, Congress passed the Hazardous and Solid Waste Amendments (HSWA) to the Resource Conservation and Recovery Act (RCRA) of 1976. Section 3004(n) of HSWA directs EPA to promulgate regulations for the monitoring and control of air emissions from hazardous waste TSDF as may be necessary to protect human health and the environment. Standards are being proposed by EPA under the authority of sections 3002 and 3004 of RCRA to reduce organic emissions from certain hazardous waste management units.

2. Proposed Standards

Standards proposed today would apply to owners and operators of permitted and interim status TSDF using tanks, surface impoundments, and containers to manage hazardous waste, as well as to hazardous waste generators using tanks and containers to accumulate large quantities of waste on-site. At these affected facilities, the proposed standards would require that specific organic emission controls (primarily application of covers with, where appropriate, control devices) be installed and operated on tanks, surface impoundments, and containers into which is placed hazardous waste having a volatile organic concentration equal to or greater than 500 parts per million by weight (ppmw). The volatile organic concentration of the waste would be determined before the waste is exposed to the atmosphere or mixed with other waste at a point as near as possible to the site where the waste is generated. This allows an owner or operator to reduce the volatile organic concentration for a specific waste to a level less than 500 ppmw through pollution prevention adjustments and other engineering techniques. Under today's proposal, if a waste stream is not determined to have a volatile organic concentration less than 500 ppmw, then the specified organic emission controls would need to be used on every tank, surface impoundment, and container into which that waste stream is subsequently placed at the affected facility. However, if during the course of treating a waste (using a means other than by dilution or evaporation into the atmosphere) the organic concentration of the waste decreases below 500 ppmw, emission controls would not be required on the subsequent downstream tanks, surface impoundments, and containers that manage this waste. The EPA encourages the use of pollution prevention techniques and treatment processes as a means of achieving the goals of today's proposed standards.

a. Tank Control Requirements. The owner or operator of a permitted or interim status TSDF tank, and the large quantity generator accumulating hazardous waste on-site in a tank for 90 days or less pursuant to 40 CFR 262.34(a), would be required to use tank organic emission controls if any hazardous waste with a volatile organic content of 500 ppmw or more is placed in the tank. The control equipment requirements would be to install, operate, and maintain either a cover connected through a closed vent system to a control device, an external floating roof, or a fixed roof with an internal floating roof. However, an owner or operator would be allowed to use a cover without a closed vent system and control device on tanks that satisfy all of the following conditions: (1) The hazardous waste placed in the tank remains quiescent (i.e., is not mixed, agitated, or aerated); (2) no waste fixation, heat using, or heat generating process is conducted in the tank; and (3) the tank capacity is either less than 75 cubic meters (m^3) (approximately 20,000 gallons); the tank capacity is less than 151 m^3 (approximately 40,000 gallons) and the waste organic vapor pressure is less than 27.6 kilopascals (approximately 4.0 pounds per square inch); or the capacity of the tank is equal to or greater than 151 m^3 and the waste organic vapor pressure is less than 5.2 kilopascals (approximately 0.75 pounds per square inch).

b. Surface Impoundment Control Requirements. The owner or operator of permitted and interim status TSDF surface impoundments would be required to use organic emission controls if hazardous waste with a volatile organic content of 500 ppmw or more is placed in the surface impoundment. The control equipment requirements would be to install, operate, and maintain a cover (e.g., air-supported enclosure) connected through a closed vent system to a control device. An owner or operator would be allowed to use a contact cover (e.g. floating membrane cover) without a closed vent system and control device on surface impoundments that satisfy both of the following conditions: (1) The hazardous waste placed in the surface impoundment remains quiescent (i.e., is not mixed, agitated, or aerated); and (2) no waste fixation, heat using, or heat generating process is conducted in the surface impoundment.

c. Container Control Requirements. The owner or operator of a permitted or interim status TSDF using containers, and the large quantity generator accumulating hazardous waste on-site in containers for 90 days or less pursuant to 40 CFR 262.34(a) would be required to use container organic emission controls if hazardous waste with a volatile organic content of 500 ppmw or more is placed in the container. Containers used for handling, preparing, or storing hazardous waste would be required to be tightly covered except when loading or unloading wastes. During container loading operations, submerged fill of pumpable hazardous waste would be required. For waste fixation operations performed directly in containers, the proposed standards would require that the container be placed in an enclosure vented through a closed vent system to a control device during the mixing of the binder with the waste.

d. Closed Vent System and Control Device Requirements. The closed vent system used to comply with the control requirements would be required by the proposed standards to be designed, installed, operated, and maintained so that there are no detectable emissions from the system, as determined by visual inspection and by monitoring using Reference Method 21 in 40 CFR part 60, appendix A. Each control device would be required to reduce the organics in the gas stream vented to it by at least 95 percent. An alternative to this requirement for enclosed combustion devices would be to reduce total organics concentration in the combustion device exhaust gas stream to 20 ppm by volume (ppmv) corrected to 3 percent oxygen on a dry basis. To document that a control device achieves the required performance level, the owner or operator would be required to

maintain on-site either documentation of the control device engineering design calculations or results of control device source tests.

e. Waste Determination Requirements. Waste determinations would only be required if an owner or operator chooses to place waste with a volatile organic concentration less than 500 ppmw in a tank, surface impoundment, or container not equipped with the specified organic emission controls, or place the waste with an organic vapor pressure below the specified limits in a tank using a cover without a closed vent system and control device. It is EPA's intention that these exceptions apply only to those units for which the owner or operator is reasonably certain that the volatile organic content or organic vapor pressure of the waste placed in the unit consistently remains below the applicable limit. The owner or operator would be required to perform periodic waste determinations using either direct measurement or knowledge of the waste. Direct measurement of the waste volatile organic concentration or organic vapor pressure would be performed using the EPA test methods and procedures being proposed as part of today's rulemaking. Knowledge of the waste would need to be supported by documentation that shows that the waste volatile organic concentration or organic vapor pressure is below the specified limit under all conditions. These direct measurement or knowledge assessments would be made for individual waste streams upstream of the affected unit or units, before the waste is exposed directly or indirectly to air and before it is mixed with other wastes. The waste determinations would need to be performed initially by the effective date of the standards and repeated at least annually and, additionally, every time there is a change in the waste being managed or in the operation that generates or treats the waste that may affect the regulatory status of the waste.

f. Monitoring and Inspection Requirements. To ensure that emission control equipment is properly operated and maintained, the proposed standards would require the owner or operator to monitor and inspect the emission control equipment at specified intervals. Continuous monitoring of control device operation would be required. This would involve the use of automated instrumentation to measure critical operating parameters that indicate whether the control device is operating correctly or is malfunctioning. Other types of emission control equipment such as covers would need to be checked by weekly visual inspections and semiannual equipment leak monitoring to ensure that equipment is being used properly (e.g., covers are closed and latched except when workers require access to a tank or container) and the equipment is being maintained in good condition (e.g., no holes or gaps have developed in cover seals).

g. Recordkeeping Requirements. The owner or operator would be required to record certain information documenting emission control equipment performance and maintenance. These records would be maintained in the facility operating log or other files kept at the facility site, and would be available for review by EPA or authorized State enforcement personnel during on-site inspections. The information to be collected and recorded would include the results of all waste determinations for volatile organic concentration and organic vapor pressure; design or performance information for closed vent systems and control devices; and emission control equipment inspection and monitoring results.

h. Reporting Requirements. The owner or operator would not be required to submit any reports to EPA unless: (1) a waste exceeds the 500 ppmw volatile organic concentration or, for certain tank applications, the vapor pressure limit, and the waste is placed in a unit without proper emission controls; or (2) a control device malfunction is not corrected within 24 hours of detection. If either of these events (referred to in this preamble as "exceedances") occur, the owner or operator would be required to maintain a record of the exceedance. For an exceedance involving waste organic concentration or organic vapor pressure, the owner or operator would be required to submit a report to EPA within 30 calendar days after the waste determination was made explaining why the waste was not managed in accordance with the requirements of the standards. For exceedances involving control device malfunctions that are not corrected within 24 hours, the owner or operator would be required to submit a report to EPA on a semiannual basis describing all of the exceedances that occurred during the past 6-month period and explaining why each exceedance occurred.

3. Summary of Impacts. The implementation of today's proposed standards for TSDF tanks, surface impoundments, and containers would achieve substantial reductions in organic emissions. The proposed standards are estimated to reduce nationwide organic emissions by 1.7 million Mg/yr. This magnitude of emission reduction is expected to have a significant positive impact on the formation of ambient ozone by eliminating emissions of a significant quantity of ozone precursors.

The proposed standards are also estimated to reduce the annual cancer incidence and the risk to the maximum exposed individual of contracting cancer posed by toxic constituents contained in the organic emissions from TSDF. The cancer risk to the entire exposed population nationwide (i.e., annual cancer incidence) is estimated to be reduced from 140 cases per year to a level of 8 cases per year. The maximum individual risk (MIR) parameter is estimated to be reduced from a level of 2×10^{-2} to a level of 5×10^{-4}. As discussed in sections III and V of this preamble, uncertainties exist in the procedures for estimating these cancer risk parameters for a variety of reasons. Nevertheless, the estimates represent a level of residual risk that is higher than the range of target risk levels for other promulgated RCRA standards. Therefore, EPA is evaluating individual toxic constituents contained in TSDF organic emissions to determine if further risk reductions can be achieved by controlling those toxic constituents in a separate rulemaking.

The total nationwide capital investment to implement the proposed standards at TSDF is estimated to be approximately $960 million. The estimated nationwide annualized cost is estimated to be approximately $360 million. Prices for commercial hazardous waste management services are estimated to increase by less than 1 percent. The nationwide quantity of waste handled by commercial hazardous waste management companies is projected to be reduced by less than 1 percent. Few, if any, facility closures are anticipated. Job losses in the hazardous waste industry are estimated to be less than 1.5 percent. Furthermore, this impact on employment does not reflect positive employment effects on industries producing the emission control equipment that would be used to comply with the proposed standards. No significant impacts are expected on small businesses.

B. Proposed Test Methods

1. Waste Volatile Organic Concentration Test Method

Today's proposed standards would allow a hazardous waste to be placed in a waste management unit not required to comply with certain control

requirements provided an owner or operator determines that all waste placed in the unit has a volatile organic concentration less than 500 ppmw. One method by which the owner or operator could perform the waste determination is by direct measurement of the waste's volatile organic concentration. The test method for determining the volatile organic concentration of a waste, Reference Method 25D, is being proposed today for addition to 40 CFR part 60 appendix A. The identical test method would also be added to "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication No. SW-846) as Test Method 5100.

The proposed test method would require representative grab samples of the waste to be collected as near as possible to the point where the waste is generated and before the point where the waste is first exposed to the atmosphere. Each sample is transferred to a container holding polyethylene glycol (PEG) and cooled to minimize loss of the volatile organics. In the laboratory, water is added to the PEG/sample mixture, and the resulting mixture is heated and purged with a stream of nitrogen (6 liters per minute at 75 °C). The purged gas stream is analyzed by directing one bleed stream to a flame ionization detector to measure the waste organic carbon content and the other bleed stream to an electrolytic conductivity detector to measure the waste halogen content. The mass of the organic carbon, calculated as methane, and halogens, calculated as chlorine, are converted by calculation to a concentration by weight of volatile organics.

2. Waste Vapor-Phase Organic Concentration Test Method

Today's proposed standards would require that organic emission controls be used on a tank into which is placed a hazardous waste containing 500 ppmw or more of volatile organics. Certain of these tanks may be equipped with a cover without a control device provided the tank volume is less than 75 m^3 or, if the volume is larger than this size, the wastes managed in the tank have an organic vapor pressure less than specified limits. Determination of the waste organic vapor pressure would involve the testing of the waste to measure the vapor-phase organic concentration of the waste and calculating the waste organic vapor pressure. A test method for determining vapor-phase organic concentration and, ultimately, waste organic vapor pressure, Reference Method 25E, is being proposed today for addition to 40 CFR part 60 appendix A. The identical test method would also be added to "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication No. SW-846) as Test Method 5110.

The proposed test method would require collection of a waste sample at the tank inlet in a headspace sample vial and transfer of the vial to a balanced pressure headspace sampler, which pressurizes the sample vial and injects a phase sample into a flame ionization detector (FID) for analysis of organic carbon. Helium is used to pressurize the sample vial, and release of the pressure injects the sample directly into the FID. The FID response is used to measure the concentration of organic carbon in the phase sample as propane. This vapor-phase organic concentration (expressed as propane) is then converted, by a calculation procedure specified in the method, to the waste organic vapor pressure.

C. Proposed Control Requirements for TSDF Miscellaneous Units

Owners and operators obtain permits to operate hazardous waste management units or technologies that are not specifically regulated elsewhere under 40 CFR part 264 by following promulgated standards under 40 CFR 264 subpart X. Permits for these units (referred to as "miscellaneous units") are issued on a case-by-case basis and must contain such terms and provisions to protect human health and the environment per the generic performance standards specified in 40 CFR 264.601. Today's proposed standards would amend § 264.601 to require that the permit terms and provisions for a miscellaneous unit being permitted under Subpart X include the appropriate emission control requirements specified by the air emission standards for certain TSDF treatment unit process vents (40 CFR 264 subpart AA), TSDF equipment leaks (40 CFR 264 subpart BB), and TSDF tanks, surface impoundments, and containers (proposed today as 40 CFR 264 subpart CC).

D. Proposed Implementation of Air Emission Standards Under RCRA at TSDF

Under current EPA practice, new RCRA standards typically apply to interim status facilities on their effective date but generally have not applied to already-permitted facilities until the facilities' permits have been modified or renewed. This practice, often referred to as the "permit-as-a-shield" policy, is discussed more fully in Section X of this preamble.

The EPA is proposing to except the control of air emissions under RCRA section 3004(n) from the "permit-as-a-shield" policy. Therefore, final air emission standards would apply to all TSDF upon the effective date (i.e., 6 months after promulgation) regardless of the status of their permit. Facilities that have already been issued a final permit before the effective date of the final standards would be required to comply with the interim status (40 CFR part 265) requirements of the final rules until the permit is reviewed or is reissued. All facilities for which permits are issued after the effective date of the final rule would be required to incorporate the requirements of the final rule in the Part B permit application and comply with the 40 CFR part 264 rules. New facilities and new units at existing facilities would be required to demonstrate in their part B permit application the means by which the requirements of the final rule will be met.

The rules would take effect 6 months after promulgation and would require that facilities implement the control and monitoring requirements by the effective date. Facilities that would be required to install control equipment would be allowed up to 18 months after the effective date to complete the design and installation if they can document that installation of the emission controls cannot be completed by the effective date. In this case, owners and operators would be required to develop an implementation schedule that indicates dates by which the design and installation of the necessary emission controls would be completed. The implementation plan would be required to be entered into the operating record.

E. Proposed Control Requirements for Hazardous Waste Generator Accumulation Tanks and Containers

Standards proposed today would affect hazardous waste generators accumulating hazardous waste on-site in tanks and containers for 90 days or less pursuant to 40 CFR 262.34(a). These tanks and containers are exempt from the RCRA subtitle C permitting requirements provided the generators comply with certain requirements including the provisions of 40 CFR 265 subpart J for tanks and 40 CFR 265 subpart I for containers. Today's proposal would amend 40 CFR 265 subparts I and J to add compliance with the organic emission control requirements relevant to tanks and containers specified in the air emission standards for certain TSDF treatment unit process vents (40 CFR part 264 subpart AA), TSDF equipment leaks (40

CFR 264 subpart BB), and TSDF tanks, surface impoundments, and containers (proposed today as 40 CFR 264 subpart CC). Therefore, generators accumulating waste in tanks and containers pursuant to 40 CFR 262.34(a) would be required to comply with additional tank and container control requirements in order to maintain permit-exempt status for these units.

Today's proposal would not apply to the accumulation of up to 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 CFR 261.33(e) in containers at or near the point of generation pursuant to 40 CFR 262.34(c). Also, today's proposal would not apply to small quantity generators of between 100 and 1,000 kilograms of hazardous waste in a calendar month who accumulate the waste in tanks and containers pursuant to § 262.34 (d) or (e).

Generator accumulation tanks and containers collect hazardous waste near the point where the waste is generated and the potential to release organics is greatest. If these units are open to the atmosphere, the majority of the organics in the waste may be emitted to the atmosphere before the waste is transferred to a TSDF waste management unit subject to the control requirements of today's proposal. Under these conditions, organic emissions from large quantity generator accumulation tanks and containers could be substantial and, consequently, decrease the organic emission reductions that are potentially achievable by requiring organic emission controls for TSDF tanks, surface impoundments, and containers.

If EPA were to delay implementation of the requirements on generator accumulation tanks and containers, then the controls at TSDF might be rendered significantly less useful, that is, no controls would be required until after significant amounts of organics had already been released from hazardous wastes into the atmosphere. Therefore, in order to effectively regulate the emissions from hazardous waste at TSDF, EPA is seeking comment on incorporating requirements at generator sites as a part of the HSWA rules proposed today. Any waste that is determined to pose an air emissions problem would thereby be controlled in all States from the time it is generated until it is treated, stored, or disposed.

A separate analysis was performed of the human health, environmental, and economic impacts expected to result from implementing the proposed control requirements on 90-day tanks and containers. The proposed standards are estimated to reduce nationwide organics emissions from 90-day tanks and containers from a baseline level of approximately 259 thousand Mg/yr to 4 thousand Mg/yr. Estimated annual cancer incidence is expected to be reduced by approximately 21 cases per year to a level of less than 1 case per year. A nationwide capital investment of approximately $41 million would be required to implement the proposed standards. The annualized cost is estimated to be approximately $10 million. Because of small cost increases to waste generators using 90-day tanks and containers, the prices of goods and services could rise slightly. The impacts of the proposed standards on the volume of wastes stored and numbers of jobs are estimated to be negligible, and employment dislocations and plant closures are unlikely.

F. Proposed Requirements for Carbon Adsorption Systems

To use carbon adsorption systems as effective control devices for reducing organic emissions from TSDF sources requires that the activated carbon in the system periodically be regenerated or replaced with fresh carbon when it becomes saturated. There is an opportunity for the organics adsorbed on the carbon to be released to the atmosphere unless the carbon regeneration or disposal is conducted under controlled conditions. There would be no environmental benefit in controlling organic emissions from TSDF sources using a carbon adsorption system if the organics controlled at one site are subsequently released to the atmosphere at another site where the carbon is sent for regeneration or disposal. To avoid this situation, requirements are proposed today that would require owners or operators using carbon adsorption systems for compliance with control device requirements in subparts AA, BB, and CC of both 40 CFR parts 264 and 265 to certify that carbon removed from the system is either: (1) Regenerated or reactivated by a process that minimizes the release of organics to the atmosphere by using effective control devices such as those now required in subpart AA, or (2) incinerated in a thermal treatment device that complies with the requirements of 40 CFR part 264 subpart O.

II. BACKGROUND

A. Regulatory Authority

Today's proposal is made under the authority of sections 3002 and 3004 of the Resource Conservation and Recovery Act (RCRA) of 1976 as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Section 3004(n) of RCRA, a provision added by HSWA, directs EPA to "* * * promulgate regulations for the monitoring and control of air emissions from hazardous waste treatment, storage, and disposal facilities, including but not limited to open tanks, surface impoundments, and landfills, as may be necessary to protect human health and the environment." The standards being proposed today implement this congressional directive by establishing nationwide regulations for the monitoring and control of air emissions from certain waste management units at TSDF subject to RCRA subtitle C permitting requirements.

The EPA is also proposing today amendments that would add to the requirements that a hazardous waste generator must comply with pursuant to 40 CFR 262.34(a) in order to exempt certain tanks and containers accumulating waste on-site from the RCRA subtitle C permitting requirements. The EPA may implement these requirements for hazardous waste generators under authority of RCRA section 3004(n), thereby making the standards applicable to hazardous waste generators as Federal law.

B. Phased Implementation of Section 3004(n)

Air emissions from TSDF sources are composed of many different types of chemical compounds. Some of these individual chemical compounds, referred to here as "constituents," are known or suspected to be toxic to humans at certain levels of exposure. It would be preferable to develop standards to control air emissions from all TSDF sources at the same time in order to best integrate implementation of the standards. However, because of the nationwide diversity and complexity of TSDF, it is a very difficult task to characterize TSDF emission sources, emission quantities, and potential emission controls. Extensive effort is required to fully understand which TSDF emission sources need to be regulated and how to best apply emission controls to those sources. Rather than delay implementation of standards until all TSDF sources could be investigated, EPA decided to implement RCRA section 3004(n) using a phased approach so that standards could be implemented for certain TSDF emission sources as quickly as possible.

The EPA is addressing TSDF air emissions primarily by implementing RCRA section 3004(n) in a phased approach through nationwide standards and, as necessary, using EPA's omnibus permitting authority under RCRA

section 3005(c)(3) while these standards are being developed (see 55 FR 25492). The omnibus permitting authority allows EPA permit writers to require, on a site-by-site basis, emission controls that are more stringent than those specified by a standard. This authority is used by EPA for those situations in which regulations have not been developed or in which unusual circumstances necessitate additional controls to protect human health and the environment.

The EPA uses the omnibus permitting authority to impose permit conditions beyond those mandated by regulations. The omnibus permitting authority is primarily used to address special site-specific circumstances that are judged necessary for protection of public health and the environment, and not to apply baseline standards that should be met by all TSDF. It is not appropriate to use omnibus permitting authority in lieu of setting standards under RCRA section 3004(n) for several reasons. First, section 3004(n) directs EPA to promulgate regulations for controlling TSDF air emissions, as necessary, to protect human health and the environment. Section 3004(n) does not allow EPA to disregard this congressional directive to promulgate regulations because section 3005(c)(3) is available to EPA permit writers, nor does section 3005(c)(3) relieve EPA of its requirement to promulgate regulations under section 3004(n). Second, establishing nationwide standards ensures that all TSDF owners and operators comply with the same set of minimum requirements. These nationwide requirements facilitate the permitting of TSDF by allowing the owner and operator seeking a permit to know in advance what control requirements, at a minimum, need to be included in the facility design in order to be issued a permit to operate. Finally, using a case-by-case permitting process for the application of air emission controls to most TSDF would require extensive industry and EPA resources, and increase the time period before controls are in place on all TSDF.

For the first phase of EPA's program to regulate air emissions under RCRA section 3004(n), EPA identified the need to develop standards for certain hazardous waste treatment processes early to coincide with the development of regulations under RCRA section 3004(m) restricting the land disposal of untreated hazardous wastes. These land disposal restrictions establish standards that require certain hazardous waste to be treated to reduce specific hazardous waste properties (e.g., concentrations of individual toxic constituents) before the waste can be placed in a land disposal unit. To address concerns about air emissions from the treatment processes expected to be used to comply with the land disposal restrictions, EPA developed air emission standards under RCRA section 3004(n) for certain treatment processes based on existing air emission standards promulgated under the Clean Air Act for similar types of air emission sources. The first phase was completed with the promulgation of final RCRA standards to reduce organic emissions vented from the treatment of hazardous wastes by distillation, fractionation, thin-film evaporation, solvent extraction, steam stripping, and air stripping, as well as from leaks in certain piping and equipment used for hazardous waste management processes (55 FR 25454, June 21, 1990).

Today's proposal is the second phase of EPA's program to regulate air emissions under RCRA section 3004(n), and addresses organic emissions from TSDF tanks, surface impoundments, containers, and certain miscellaneous units. In both the first and second phases, standards are developed that control organic emissions as a class (as opposed to constituent-by-constituent). The regulation of organics as a class is relatively straightforward because it can be accomplished by a single standard, whereas the control of individual toxic constituents will require multiple standards for which the EPA has not completed sufficient analysis at this time. Implementation of today's proposal would substantially reduce emissions of ozone precursors as well as toxic constituents while EPA analyzes the human health and environmental impacts associated with individual toxic constituents that compose the organic emissions as part of the third phase of the program. This approach continues the approach used in the first phase where the "* * * standards achieve significant reductions in emissions and risk and, that after control, the vast majority of facilities are well within the risk range of other RCRA standards" (55 FR 25470).

For the third phase, EPA may issue regulations to address the risk remaining after promulgation of the first two phases. The EPA has initiated an effort to update and improve the data base used for analyzing the human health and environmental impacts resulting from TSDF air emissions. The EPA expects that, if regulations are necessary in the third phase, they will likely pose controls on individual toxic constituents. The EPA believes that the control of organics as a class followed by controls for individual toxic constituents, if necessary, will result in comprehensive standards that are protective of human health and the environment.

C. Relationship of Today's Proposed Standards to Other RCRA Rules

1. Hazardous Waste Toxicity Characteristics

One of the procedures by which EPA defines wastes as "hazardous" is by identifying properties or "characteristics" of wastes which, if exhibited by a waste, indicate that the waste will pose hazards to human health and the environment if its management is not controlled. Recently, EPA issued final rules modifying the procedure to determine if a waste exhibits the characteristic of toxicity (55 FR 11798, March 29, 1990). Amendments to 40 CFR part 261 added 25 organic constituents to the toxicity characteristic list of constituents in 40 CFR 261.24 and replaced the Extraction Procedure (EP) in appendix II with the Toxicity Characteristic Leaching Procedure (TCLP). These changes are effective September 25, 1990, and will likely result in large quantities of wastewater and additional quantities of sludges and solids being identified as hazardous waste. The estimated nationwide impacts presented today for the proposed standards do not include the additional impacts resulting from the new toxicity characteristic constituent list and TCLP. However, the additional waste types and quantities would be subject to the control requirements of today's proposed standards.

The EPA requests comments (including data and supporting documentation) on how these additional waste types and quantities would affect the emission control, risk, and cost impacts associated with this rulemaking. The EPA will update the analysis before promulgation of this rule based on additional documented data received or gathered by EPA.

2. Land Disposal Restrictions (LDR)

The EPA has already promulgated and is continuing to develop LDR that require hazardous wastes to be treated to reduce the toxicity or mobility of the waste before it can be placed in a land disposal unit. The affected land disposal units include certain surface impoundments, and all waste piles, landfills, and land treatment units that do not meet the statutory no migration standards. Surface impoundments used for treatment of hazardous waste are exempt from the LDR if treatment residues that do not meet the treatment standards are removed for subsequent

management within one year of placement in the surface impoundment.

The LDR establish specific treatment standards that must be achieved before placing the waste in the land disposal unit. Treatment standards are expressed as either concentration limits or specified technologies. These standards are developed on the basis of using the best demonstrated available technology (BDAT). When an LDR treatment standard is expressed as a concentration limit (i.e., performance level), the owner or operator may use any nonprohibited technology to treat the waste to meet the standard. However, when an LDR treatment standard is expressed as a specific technology or technologies, the owner or operator must treat the waste using the specified technologies prior to land disposal.

The EPA is developing the LDR in stages. Waste specific prohibitions on land disposal have been promulgated for certain spent solvent wastes (40 CFR 268.30); dioxin-containing hazardous wastes (40 CFR 268.31); the "California list" wastes (40 CFR 268.32); "First Third" set of listed wastes (40 CFR 268.33); "Second Third" set of listed wastes (40 CFR 268.34); and, recently, the "Third Third" set of listed wastes (55 FR 22520, June 1, 1990). The TSDF air emission standards being proposed today would be promulgated after the date that LDR are in effect for all wastes identified or listed as hazardous as of November 8, 1984.

3. Existing TSDF Air Emission Standards

The EPA has already developed RCRA standards to control organic emissions from certain hazardous waste treatment processes. Air emissions from thermal destruction treatment processes (i.e., hazardous waste incinerators) presently are regulated by 40 CFR 264 subpart O. Air emissions from other types of noncombustion treatment processes are controlled by the air standards for TSDF treatment unit process vents and equipment leaks (subparts AA and BB in 40 CFR parts 264 and 265). Today's proposed standards would control air emissions from TSDF sources not regulated by these other RCRA rules.

The 40 CFR 264 subpart O standards establish three performance standards for hazardous waste incinerators limiting emissions of organics, particulate matter, and hydrogen chloride. Organic emissions are controlled by requiring a hazardous waste incinerator to achieve a destruction and removal efficiency (DRE) of 99.99 percent for each principal organic hazardous constituent designated for each waste feed. The EPA has proposed amendments to these regulations to improve control of toxic metals, hydrogen chloride, and residual organic emissions (55 FR 17682; April 27, 1990). In addition, EPA has promulgated rules to establish emission controls for boilers and furnaces burning hazardous wastes (56 FR 7134, February 21, 1991).

The Subpart AA standards in 40 CFR parts 264 and 265 are applicable to vents used for distillation, fractionation, evaporation, solvent extraction, air stripping, and steam stripping waste operations that manage hazardous waste with a total organics concentration equal to or greater than 10 parts per million by weight (ppmw). The affected vents include all vents on the process units, vents on condensers serving these units, and vents on tanks through which the organic emissions from the process units are vented. These standards require owners or operators of TSDF that use the affected waste treatment processes to either: (a) Reduce total organic emissions from all affected vents at the facility to less than 1.4 kilograms per hour (3 pounds per hour) and 2,800 kilograms per year (3.1 tons per year), or (b) install and operate a control device(s) that reduces total organic emissions from all affected vents at the facility by 95 percent by weight or, for enclosed combustion control devices, to a total organic compound concentration of 20 parts per million by volume (ppmv) expressed as the sum of actual compounds present.

The Subpart BB standards in 40 CFR parts 264 and 265 control emissions resulting from leaks associated with certain types of TSDF process equipment. These standards require implementation of a leak detection and repair program for pumps and valves, and the installation and operation of certain equipment on compressors, pressure-relief devices, sampling connection systems, open-ended valves or lines, flanges or other connectors, and associated air emission control devices. The requirements apply to TSDF where the equipment specified above contains or contacts hazardous waste which contains organic concentrations of 10 percent or greater by weight.

4. Corrective Actions

Under the authority of RCRA section 3004(u), EPA has proposed regulations to address releases of hazardous waste or hazardous constituents from solid wastes management units (SWMU's) that pose a threat to human health and the environment (55 FR 30798; July 27, 1990). Because this authority applies to contamination of soil, water, and air media, organic emissions from SWMU's at some TSDF would be addressed by the corrective action program. The proposed regulations would establish health-based trigger levels measured at the TSDF boundary for determining whether further remedial studies are required to assess air emissions from a particular SWMU. Health-based cleanup standards would then be set for air emission levels that exceed acceptable health-based levels at the point at which actual exposure occurs. When such exposure is determined either through monitoring or modeling techniques, corrective action would be required to reduce such emissions at the point of exposure.

The corrective action program is designed to achieve site-specific solutions based on an examination of a particular TSDF and its environmental setting. It is not intended to set national standards that regulate organic emissions from all TSDF. At sites where there are releases from SWMU's to the atmosphere, organic emissions will be controlled based on site-specific exposure concerns. Furthermore, releases from the SWMU's that contain nonhazardous solid wastes will also be subject to corrective action. Therefore, for air emissions, corrective action, in a sense, is designed to address expeditiously threats to human health and the environment that are identified prior to implementation of the more comprehensive standards being proposed today. In addition, in some respects, since corrective action can address a wider universe of SWMU's, it will also address some exposure concerns that today's proposed standards do not address.

5. Hazardous Waste Transporters

Regulations in 40 CFR part 263 establish standards which apply to persons transporting hazardous waste within the United States if the transportation requires a manifest under 40 CFR part 262. For a portion of these standards, EPA has adopted certain relevant regulations of the Department of Transportation (DOT) governing the transportation of hazardous materials (49 CFR parts 171 through 179). Compliance with the existing 40 CFR part 263 and 49 CFR parts 171–179 standards is expected to effectively control organic emissions during transit of hazardous wastes to TSDF. Therefore, the standards proposed today would not apply to hazardous waste transporters.

D. Relationship of Today's Proposed Standards to CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. 9601 et. seq., authorizes EPA to undertake removal and remedial actions to clean up hazardous substance releases. Removal actions typically are short-term or temporary measures taken to minimize exposure or danger to humans and the environment from the release of a hazardous substance. Remedial actions are longer-term activities that are consistent with a permanent remedy for a release. On-site remedial actions are required by CERCLA section 121(d)(2) to comply with the requirements of Federal and more stringent State public health and environmental laws that are applicable or relevant and appropriate requirements (ARAR's) to the specific CERCLA site. In addition, the National Contingency Plan (NCP) provides that on-site CERCLA removal actions "should comply with the Federal ARAR's to the extent practicable considering the exigencies of the circumstances" (40 CFR 300.65(f)). Today's proposed standards may be considered ARAR's for certain on-site remedial and removal actions.

A requirement under a Federal or State environmental law may either be "applicable" or "relevant and appropriate," but not both, to a remedial or removal action conducted at a CERCLA site. "Applicable requirements" as defined in the proposed revisions to the NCP means those cleanup standards, standards of control, and other substantive environmental protection requirements, criteria, or limitations promulgated under Federal or State law that specifically address a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance found at a CERCLA site (40 CFR 300.5 (proposed), 53 FR 51475; December 21, 1988). "Relevant and appropriate requirements" means those Federal or State requirements that, while not applicable, address problems or situations sufficiently similar to those encountered at the CERCLA site that their use is well suited to the particular site (53 FR 51478).

Some waste management activities used for remedial and removal actions to clean up hazardous organic substances require the use of tanks, surface impoundments, and containers. For example, hazardous organic liquids and surface waters contaminated with hazardous organic wastes may be treated on-site using destruction, detoxification, or removal processes that occur in tanks or surface impoundments. On-site solvent washing of soils contaminated with hazardous organic sludges may be performed in a tank or container. Hazardous wastes in leaking drums may be repacked in new containers for treatment and disposal off-site.

The organic emission control requirements proposed today would be "applicable" to on-site remedial and removal actions that use tanks, surface impoundments, and containers to manage substances identified or listed under RCRA as hazardous waste and containing more than 500 ppmw of volatile organics. In addition, off-site storage, treatment, and disposal of all wastes classified under RCRA as hazardous waste must be performed at a TSDF permitted under RCRA subtitle C. Thus, CERCLA wastes that are defined as hazardous under RCRA, contain more than 500 ppmw of volatile organics, and are shipped off-site for management in tanks, surface impoundments, and containers, would be subject to today's proposed standards like any similar RCRA hazardous waste. Also, the proposed standards may be "relevant and appropriate" to on-site CERCLA removal and remedial actions that use tanks, surface impoundment, and containers to manage substances which contain volatile organics that are not covered by this rule (e.g., hazardous wastes with volatile organic concentrations less than 500 ppmw, or nonhazardous wastes containing volatile organics).

On the other hand, today's proposed standards do not specify control requirements for waste piles, landfills, and land treatment units which manage hazardous wastes at TSDF. Therefore, the proposed standards would not be "applicable" to excavation, capping of wastes, land treatment, land farming, in-situ treatment activities, and other activities involving waste piles and landfills at CERCLA sites. Although in most cases EPA does not expect the proposed standards to be "relevant and appropriate" to these types of units at CERCLA sites, remedial and removal actions performed in waste piles may be similar in nature and scale to the waste management activities performed in surface impoundments; and waste fixation may involve the same basic process and air emission mechanism regardless of whether the mixing of the waste and binder is conducted in a tank, surface impoundment, container, waste pile, landfill, or land treatment unit. Thus, the EPA expects that the proposed standards may be "relevant and appropriate" for (1) storage of waste containing more than 500 ppmw volatile organics in waste piles, and (2) fixation of wastes containing more than 500 ppmw volatile organics in landfills, waste piles, or land treatment units.

III. Sources and Emissions

A. Overview of Source Category

Hazardous waste TSDF are facilities where hazardous wastes are treated, stored, and/or disposed. The hazardous waste may be generated at the same site where the TSDF is located or may be generated off-site and transported to the TSDF for management. The EPA has conducted a number of surveys to collect information about the TSDF industry. Data from these surveys indicate that there are more than 2,300 TSDF, and approximately 96 percent of the hazardous waste managed at TSDF is generated and managed on the same site. The survey data identify more than 150 different industries, primarily manufacturing, that generate hazardous waste. Approximately 500 TSDF are commercial facilities that manage hazardous waste generated by others.

The types of hazardous wastes managed at TSDF and the waste management processes used are highly variable from one facility to another. The physical characteristics of wastes managed at TSDF include dilute wastewaters (representing more than 90 percent by weight of the total waste managed), organic and inorganic sludges, and organic and inorganic solids. Waste management processes differ according to waste type and include storage and treatment in tanks, surface impoundments, and waste piles; handling or storage in containers such as drums, tank trucks, tank cars, and dumpsters; and disposal of waste by incineration, land treatment, injection into deep wells, or placement in landfills. In addition, hazardous waste may be managed in miscellaneous units that do not meet the RCRA definition of any of the processes listed above. Hazardous waste may also be handled in research, development, and demonstration units pursuant to requirements specified in 40 CFR 270.65.

The remainder of this section describes TSDF emission sources, discusses the analytical basis for estimating TSDF emissions and other impacts, and presents the rationale for selecting the hazardous waste management units to be controlled by today's proposed standards.

B. Analytical Basis for Impacts Estimation

1. Approach

Sufficient data concerning the wastes managed and waste management practices used are not available to perform a site-by-site impact analysis of each TSDF location in the United States. Therefore, EPA used computer models to estimate total organic air emissions from TSDF, the risk of contracting cancer posed by exposure to toxic constituents contained in these organic emissions, and the costs to control the emissions. To compare different regulatory strategies for controlling TSDF organic air emissions, EPA developed a national impacts model. This model calculates nationwide impacts through summation of approximate individual facility results. The primary objective and intended use of the national impacts model are to provide reasonable estimates of TSDF impacts on a national level. Because of the complexity of the hazardous waste management industry and lack of detailed information about every TSDF location, the national impacts model was developed to use nationwide average data for the TSDF locations where the site-specific data were incomplete or not available. Consequently, the national impacts model estimates are not considered by EPA to be accurate on an individual facility basis. However, on a nationwide basis, the national impact model estimates are a reasonable approximation and provide the best basis presently available for evaluating different regulatory strategies for controlling TSDF air emissions.

The national impacts model is not suitable for evaluating certain health impacts because the health effect parameters used to measure these impacts are not cumulative on a nationwide basis and are only meaningful for a specific site. Therefore, a second model was used to evaluate the cancer and noncancer health impacts resulting from exposure of the public to the organic emissions released from a specific TSDF site that was selected to represent a reasonable worst case analysis.

2. National Impacts Model

a. Overview. The national impacts model is a complex computer program that processes a wide variety of information and data concerning the TSDF industry in the United States. The data processed by the model include results from nationwide surveys of the TSDF industry, characterizations of TSDF processes and wastes, as well as engineering simulations of the relationships between: (1) Waste management unit type, the quantity and composition of the waste managed in the unit, and the air emission mechanism; (2) air emission control technology, control efficiencies, and associated capital and operating costs, and (3) population exposure to TSDF air emissions and resulting nationwide cancer incidence.

The national impacts model computer code is composed of subroutines that identify for each TSDF location in the data base the types of waste management units used and the volumes and characteristics of wastes managed; assign chemical properties to the waste types and emission controls to the waste management unit types; and calculate uncontrolled emissions, emission reductions, control costs, and health impacts. The computer logic is also designed to perform waste stream mass balances to account for the reduction in the organic content of the waste stream resulting from biodegradation and volatilization prior to the management of the waste in downstream units; test each waste stream for volatile organic content and vapor pressure based on models derived from laboratory tests; determine total organics by volatility class for each waste stream; and check for waste form, waste code, and management unit compatibility.

The input data required to run the national impacts model was assembled into specific input data files. The content of the major data files are briefly described below along with how the information is used by the national impacts model. A detailed description of the data files and the national impacts model is presented in appendices to the background information document (BID).

The computer model accesses the input data files and retrieves the information or data required to perform a particular calculation. When data needed for a calculation are missing for a TSDF location, the computer model logic assigns appropriate default values in order to complete the calculation. The default value assigned to a particular parameter for input into the model was selected based on national average data. For example, a given quantity of a waste is reported in the input data base as being processed in treatment tanks at a particular TSDF location but no other information is available about the tanks. Because the air emissions from managing this quantity of waste vary depending on the type of treatment tanks used (e.g., open-top, covered, aerated), the national impacts model distributes this waste quantity among the different treatment tank subcategories using national average distribution frequencies computed based on treatment tank management practices used nationwide at the TSDF locations for which this information is available. The need to make certain assumptions about waste characteristics and management practices used at some TSDF introduces a degree of uncertainty into the impact analysis. Because the actual conditions at a particular TSDF location may vary significantly from national average conditions, EPA does not consider the national impacts model estimates to be accurate on an individual facility basis. However, considering the large number of TSDF in the United States, EPA believes that using national average values for TSDF locations where some site-specific data are not available provides a reasonable approach for approximating nationwide TSDF impacts.

b. TSDF Industry Profile Data. The industry profile data file identifies the name, location, primary standard industrial classification (SIC) code, waste management processes, waste types, and annual waste throughputs for each active TSDF located in the United States with a few exceptions. The data file does not include TSDF that manage less than 0.01 Mg/yr (22 lb/yr) of hazardous waste or that manage exclusively State-designated hazardous wastes (rather than wastes designated as hazardous under RCRA). The industry profile data file also does not include facilities where all available data were classified as confidential business information. The exclusion of these active facilities from the data file does not significantly affect the nationwide impact estimates results because the excluded facilities are either very small emission sources or account for only a very small percentage of the facilities managing more than 0.01 Mg/yr.

The industry data were obtained from three principal sources: a 1986 screening survey of hazardous waste treatment, storage, disposal, and recycling facilities (referred to here as the "1986 screening survey"); the hazardous waste data management system's RCRA Part A permit applications; and a 1981 survey of hazardous waste generators and TSDF regulated under RCRA. The 1986 screening survey covered more than 5,000 potential TSDF nationwide. Data from that survey for more than 2,300 facilities were incorporated into the industry profile data base for use in the industry analysis. Surveyed facilities that were not included in the data base

were omitted primarily because they were found to be inactive. These facilities include former TSDF that have ceased all hazardous waste management operations, TSDF that are closing and did not manage waste in 1985, and facilities that do not treat, store, dispose of, or recycle hazardous waste.

The 1986 screening survey contained the most recent industry information available at the time EPA performed its analysis. Therefore, data from this survey were the primary source used to identify currently active TSDF, their waste quantities, and their operating waste management processes. However, because that survey did not contain site-specific information that identifies specific waste codes and the processes by which they are managed, the other two data sources were used as the basis for the waste data and other site-specific data. The industry data are used in the impacts model to define the location and the SIC code for each facility, and to identify the waste management units used at each facility as well as the types and quantities of hazardous waste managed in each unit.

c. Waste Characterization Data. The waste characterization data file consists of waste data representative of typical hazardous wastes handled by TSDF, classified by SIC code. For each SIC code, the waste characterization data file identifies the waste types typically managed by the industry sector (using RCRA waste codes), the physical/chemical forms of the waste managed (e.g., inorganic sludges, organic liquids, etc.), and the typical chemical composition (i.e., the constituents and their concentrations) for each listed waste type. The hazardous waste data are assigned to the specific TSDF locations listed in the industry profile data base by the SIC code and the RCRA waste codes identified for each facility.

Information compiled for the waste characterization data file was obtained primarily from five existing data bases: (1) The previously mentioned 1981 survey of hazardous waste generators and TSDF regulated under RCRA, (2) the Office of Solid Waste Industry Studies Data Base (ISDB), (3) a hazardous waste data base for wastes having RCRA waste codes beginning with the letter "K," (4) the waste stream data base for the Office of Solid Waste "Waste—Environment—Technology" (WET) model, and (5) a data base developed by the State of Illinois Environmental Protection Agency. Information from EPA field reports was also used. The data file contains one waste characterization for each waste code in each SIC code even where different data were available. When explicit data were not available, approximations were used to fill in the missing data. For example, when waste composition data were not available for a particular waste stream, default chemical composition values (derived from information in data bases for similar waste stream applications) were substituted for the missing data. The waste characterization data file is used in the national impacts model to identify representative compositions for hazardous wastes managed at a TSDF.

More than 4,000 waste constituents were identified from the waste data as being managed nationwide at TSDF. To reduce the total number of chemical constituents assessed by the national impacts model, surrogate waste categories were defined to represent different groupings of constituents that share similar chemical, physical, and biological properties affecting organic emissions. Each surrogate waste category was defined to represent a subset of actual organic compounds based on vapor pressure, Henry's law constant, and biodegradability. When a particular chemical compound is indicated in the waste characterization data base to be managed at a specific TSDF location, property data defined for the surrogate waste category to which that compound has been assigned are used for developing air emission factors.

d. Air Emission Data. Air emission factors are used by the national impacts model to calculate the quantity of volatile organics contained in a particular waste that would be emitted to the atmosphere when the waste is placed in a particular type of waste management unit. Emission factors for the national impacts model were derived using emission models to calculate emission factors for the different surrogate waste categories when managed in the different types of waste management units. The emission models were either developed specifically for this analysis or adapted from models described in the literature. The models used are described in an EPA report entitled "Hazardous Waste Treatment, Storage, and Disposal Facilities (TSDF)—Air Emission Models," which was prepared as a part of the background study for the standards proposed today. Predictions using the emission models were compared with field test data. In general, the emission factors estimated by the models agreed with the measured emission rates within an order of magnitude. Considering that the emission factors are used by the national impacts model to represent nationwide average emission rates, this level of agreement between the emission factors and measured emission rates is reasonable. A description of the individual emission models used and a summary of the comparisons of measured and estimated emissions for each model are presented in appendix C of the BID.

Using the emission models, organic emissions were estimated by surrogate waste category for representative model units for each waste management unit type (e.g., aerated treatment tanks) that span the range of design characteristics and operating practices typically used nationwide. The model unit emission estimates for a particular waste management unit type were then combined into weighted emission factors by surrogate waste category to represent a "national average model unit" by calculating the weighted average of the emissions estimates using the nationwide distribution of the unit sizes (e.g., waste management unit capacity) as the basis for weighting. These weighted emission factors are expressed in terms of the quantity of organic emissions per megagram of waste throughput managed. The weighted emission factors were then compiled into an emission factor data file for use by the national impacts model. A detailed discussion of the emission factor data file is presented in Appendix D of the BID.

e. Health Effects Data. The EPA uses the Human Exposure Model (HEM) to estimate the magnitude and location of long-term average ambient concentrations of an air pollutant in the vicinity of an emitting source, and to estimate the number of people living in the vicinity of this source. The HEM incorporates an atmospheric dispersion model that includes local meteorological data with a population distribution estimate based on 1980 Bureau of Census data to calculate public exposure. The HEM output was adapted for use by the national impacts model to estimate annual cancer incidence (i.e., the number of cancer cases per year nationwide resulting from exposure to TSDF emissions) for the population living within 50 kilometers of each TSDF. The HEM was applied to TSDF by first running the model for each individual TSDF location listed in the industry profile data file using a standardized set of parameters for all locations. The HEM results were then compiled into an incidence data file which was subsequently adjusted by the national impacts model to reflect the individual TSDF site-specific conditions

based on estimated total annual organic emissions from each TSDF and a composite unit risk factor. The individual facility incidence estimates were then summed to obtain a nationwide cancer incidence value.

A unit risk estimate for a carcinogen is defined as the lifetime cancer risk occurring in a hypothetical population in which all individuals are exposed throughout their lifetime (assumed to be 70 years) to an average of 1 $\mu g/m^3$ of the pollutant in the air they breathe. Unit risk estimates are typically derived by mathematical extrapolation from studies of people exposed in their workplace or from animal studies. The linear non-threshold model is considered to be a viable model for any carcinogen, and unless there is evidence to the contrary, it is used as the primary basis for risk extrapolation to the low levels of exposure in the ambient air. The unit risk values estimated by this method provide a plausible, upperbound limit on public risk at lower exposure levels if the exposure is accurately quantified; that is, the true risk is unlikely to be higher than the calculated level and could be substantially lower. A more detailed discussion of the unit risk estimate method used by EPA is presented in appendix E of the BID.

To address the difficulty of dealing with the large number of toxic chemicals that are managed at TSDF nationwide, EPA used a composite unit risk estimate approach. Because individual unit risk factors have not been developed for all of these toxic chemicals, EPA could only include those carcinogens for which factors were available in the computation of the composite unit risk factor. The composite unit risk factor used for the nationwide impact estimates was calculated as the weighted average of the individual unit risk factors for 52 organic compounds that have been identified as carcinogens and are managed at TSDF. Each unit risk factor for a specific compound was weighted on the basis of the estimated nationwide emissions for that compound to account for the varying quantities in which the different organic compounds are emitted from TSDF. The specific calculations of the composite unit risk factor are presented in appendix E of the BID.

Uncertainties exist in the composite unit risk factor because of difficulties in averaging unit risk factors for specific constituents. For example, approximately one-half of the composite unit risk factor value is contributed by the estimated dioxin emissions from TSDF. The individual unit risk factor for dioxin is substantially higher than the individual factors for the other 51 compounds used to calculate the composite unit risk factor. Survey data used by EPA for the national impacts analysis indicated that some TSDF manage dioxin-containing wastes. However, the majority of TSDF are not expected to manage these wastes. The potency of the dioxin in these wastes may vary significantly depending on the particular dioxin isomer present. Because the survey data does not identify isomer forms in the waste, EPA made the conservative assumption that the dioxin is present in its most potent isomer form (i.e., tetrachlorodibenzo(2,3,7,8)-p-dioxin). There is controversy in the scientific community about the mechanism by which dioxin causes cancer. If EPA has modified the method by which it estimates risk from dioxin by the time EPA is reassessing the impact analysis for this rule, EPA will use the new methodology. In contrast, certain dioxin-containing wastes (e.g. waste codes F020, F021, F023, F026, F027, and F028) were not included in the survey data because these wastes were listed after the survey was completed. Thus, the computed composite unit risk factor does not account for dioxin emissions from all dioxin-containing wastes managed in TSDF. The EPA is requesting comments regarding the methodology used to address the computation of a composite unit risk factor.

f. Emission Control Data. Data files were assembled containing information about emission controls applicable to each type of TSDF waste management unit for calculating nationwide controlled emissions, control costs, and other environmental impacts. For the emission controls selected for a particular regulatory strategy, these files provide emission control efficiencies, and capital investment and annual operating cost factors. Emission control efficiencies were selected for each emission control type and TSDF waste management unit application using the best available information from field source tests, laboratory test data, empirical emission models, and theoretical chemistry relationships. These emission control efficiencies are discussed further in Section IV and appendices D and H of the BID.

The nationwide costs to the TSDF industry of implementing a particular regulatory strategy are calculated as a function of the waste quantities identified in the industry profile data base. Cost estimates were first prepared for national average model TSDF waste management units using standard cost engineering procedures and practices. The same model units defined for the air emission estimates were used for the control cost estimates. These control estimates were divided by the model unit waste throughput to obtain a capital investment factor and an annual cost factor. The appropriate cost factors for the emission controls that would be required by a particular regulatory strategy for each waste management unit type are then multiplied by the total nationwide waste quantity tabulated by the national impacts model for the waste management unit type. These cost values were then summed to obtain total nationwide capital investment and annual cost impacts to the TSDF industry. A detailed description of the cost estimating procedure used for each emission control and waste management unit combination is presented in appendix H of the BID.

The emission controls used to reduce TSDF air emissions may create additional environmental impacts (e.g., disposal of saturated carbon from carbon adsorption systems, nitrogen oxide air emissions from thermal vapor incinerators) as well as energy impacts (e.g., fuel consumption to produce steam for carbon regeneration). These cross-media impacts (i.e., water and solid waste impacts), secondary air impacts (i.e., other air pollutant emissions resulting from the application of organic emission controls), and energy impacts were calculated for the regulatory options using the same basic approach used to estimate control costs except factors appropriate for estimating air, water, solid waste, and energy impacts were developed. A detailed description of the procedure used to estimate cross-media, secondary air emission, and energy impacts is presented in appendix K of the BID.

g. National Impacts Model Baseline Simulation. To estimate the nationwide human health and environmental impacts expected to occur if a new standard is promulgated, EPA calculates the impacts from implementing the standard (e.g., organic emission reduction) with respect to the impacts that would occur in the absence of implementing the standard. Often, the current levels of air emissions from a source and the associated health impacts are used as the reference point or "baseline" from which the emission reduction and other impacts are determined. However, because of other EPA rulemakings under RCRA presently in progress, the level of nationwide TSDF organic emissions by the time today's proposed regulation would be promulgated is expected to be

significantly different from the current emission level. The existing RCRA air emission standards and LDR described in section II will affect organic emissions from many TSDF emission sources. Therefore, EPA established the baseline level of organic emissions from which the impacts of today's proposed regulation are determined assuming that the existing RCRA air emission standards and LDR have been implemented. Other organic emission control requirements applicable to TSDF, such as the RCRA corrective action program and any State standards, were not included in the baseline calculations because these requirements are site-specific rather than nationwide control requirements and, thus, are difficult to characterize.

The LDR for many listed wastes have only recently been finalized and many of the treatment standards are expressed as performance standards for certain constituents in the treatment residue rather than as specific technology requirements. Therefore, EPA is not certain at this time as to how the LDR will ultimately impact TSDF air emissions. For the nationwide impact analysis, EPA first needed to forecast the approaches TSDF owners and operators would most likely choose to implement the LDR for specific wastes types. Using available information, EPA made certain assumptions regarding the general or average response of the hazardous waste management industry to complying with the LDR. These assumptions are: (1) All wastes currently land treated will be incinerated with the exception of high-solids content waste mixtures, (2) all organic liquids and organic sludges/slurries currently placed in landfills and waste piles will be incinerated, (3) all dilute aqueous liquids, aqueous sludges/slurries, and high-solids content waste mixtures will be converted by waste fixation into a solid material and then placed in a landfill, (4) all treatment surface impoundments will either be maintained as surface impoundments and dredged once a year or converted to open tanks, and for both cases it is assumed that there will be no change in emissions, emission reduction, and costs of control, (5) all waste fixation processes will use a chemical process involving the mixing of the waste with a binder to form a mixture that upon curing yields a solid material, and (6) the waste management unit treating a waste to comply with the LDR treatment standards is the last unit prior to disposal of the waste in the waste management sequence used at a particular TSDF site (i.e., LDR treatment unit is located downstream of all other waste storage and treatment units).

The need to use assumptions about how TSDF owners and operators will comply with the LDR adds uncertainty to the national impacts estimates. The EPA selected a combination of LDR assumptions to represent a plausible yet conservative TSDF waste management sequence to apply organic emission controls. For example, because the analysis assumes that treatment to comply with the LDR occurs as the last step prior to disposal at every TSDF location, the national impacts model calculates the cost of using organic emission controls on every tank, surface impoundment, and container used at a particular TSDF site to manage a waste stream selected for regulation. In actuality, EPA expects that at many TSDF sites, the owner or operator would treat the waste to comply with the LDR (as well as for other reasons) at an earlier step in the waste management sequence reducing the organic content of the waste and, thus, likely avoiding the need to use emission controls on the downstream tanks, surface impoundments, and containers. Similarly, the analysis assumes that all dilute aqueous liquids, aqueous sludges/slurries, and high-solids content waste mixtures containing organics are treated at each TSDF site using a waste fixation process. As a result of this assumption, the national impacts model calculates the cost of applying enclosures and control devices to control organic emissions from the fixation of these wastes. Recent surveys conducted by EPA suggest that TSDF owners and operators may choose to use other treatment processes and may fixate significantly less quantities of wastes containing organics than is calculated by the national impacts model.

To be able to consider the degree of uncertainty in EPA's assumptions for estimating nationwide impacts in the selection of the final standards, EPA is requesting comment from TSDF owners and operators as to how they are currently or are planning to comply with other hazardous waste management regulatory requirements such as the land disposal restrictions. Specifically, information is requested regarding the extent to which TSDF owners and operators are continuing to use land treatment units for liquid, slurry, and sludge type wastes; using waste incineration for disposal of organic liquids and organic sludges/slurries; stabilizing dilute aqueous liquids and aqueous sludges/slurries by waste fixation for disposal in landfill; replacing treatment surface impoundments with tanks; and locating LDR treatment units upstream of other storage and treatment units. Prior to finalizing this rule, EPA will reevaluate the assumption on what an owner or operator would do in response to the land disposal restrictions. If appropriate, EPA will modify the treatment model used to estimate the effects of this rule.

3. Site-Specific Impacts Model

The national impacts model is not appropriate for evaluating certain health impacts because these health parameters are only meaningful for a specific site. Therefore, EPA used a second site-specific model to evaluate the maximum lifetime cancer risk to the most exposed individual, and both long-term (chronic) and short-term (acute) noncancer health effects for a specific TSDF site. This site was chosen to represent conditions near the upper end of the range of expected exposures to toxic constituents in TSDF organic emissions.

The TSDF site was selected for the analysis on the basis of: (1) the availability of sufficient information to characterize it for detailed emission modeling and dispersion modeling, (2) the presence of a variety of emission sources, and (3) the management of sufficient waste volumes to maximize emissions. Emission models were used to estimate the magnitude of the organic emissions from each source. Dispersion models were used to estimate ambient concentrations of organics that people would be exposed to around the facility as a result of the facility emissions. Site-specific data inputs to the modeling effort included physical details of each waste management unit, the hazardous waste types and volumes handled by the units, the physical location of the units relative to the property line of the facility, and local meteorological data. Additional details on the detailed facility modeling are presented in Appendix J of the BID.

Estimation of the ambient concentrations of organics that people would be exposed to around the facility as a result of the facility emissions allowed site-specific cancer and noncancer health effects to be evaluated. A composite unit risk factor was applied to the estimated ambient organic concentrations to estimate maximum individual cancer risk. The same composite unit risk factor used to estimate nationwide cancer incidence was also used for the site-specific modeling. Reference doses were applied to the estimated ambient organic concentrations to evaluate noncancer health effects.

C. TSDF Organic Emission Sources

1. Tanks

Tanks are used at TSDF for storage and for treatment of hazardous waste. Most TSDF storage tanks are presently either open-top (i.e., uncovered) or are covered and vented to the atmosphere. A few storage tanks are vented to a control device. Emissions from tanks occur as a result of evaporation at the liquid surface of the waste. For open tanks, the evaporated organics (i.e., vapors) are dispersed into the atmosphere by diffusion, wind, or displacement during tank filling. Covering a tank lowers organic emissions, but emissions still occur through the cover vents as a result of the displacement of vapors during filling operations or by diurnal temperature changes. Emissions from treatment tanks that use aeration, agitation, or mixing operations tend to be higher than for storage tanks. However, emissions from tanks used for treatment processes such as clarification, sedimentation, or neutralization where no mechanical mixing is involved and the waste remains in a "quiescent" state are similar to emissions from storage tanks.

As a group, tanks comprise the largest TSDF organic emission source. Estimated current nationwide organic emissions from storage tanks at TSDF are approximately 756,000 Mg/yr. Current nationwide organic emissions from treatment tanks managing quiescent wastes (referred to here as "quiescent treatment tanks") are estimated to be approximately 48,000 Mg/yr. Current nationwide organic emissions from treatment tanks managing nonquiescent wastes (referred here as "nonquiescent treatment tanks") are estimated to be approximately 440,000 Mg/yr. The EPA does not expect that additional controls will be applied to TSDF tanks as result of existing RCRA rules with the exception of some tanks used as an integral component of treatment processes regulated by subpart AA of 40 CFR parts 264 and 265 (e.g., condensate receiving tanks used with batch distillation processes). Therefore, baseline emissions are estimated to be the same as current emissions.

2. Surface Impoundments

Surface impoundments are also a large source of TSDF organic emissions. Similar to open-top tanks, emissions from surface impoundments are released directly to the atmosphere from the exposed waste surface. Current organic emissions from storage and quiescent treatment surface impoundments are estimated to be approximately 210,000 Mg/yr nationwide. Current nationwide organic emissions from nonquiescent treatment impoundments are estimated to be approximately 74,000 Mg/yr.

For the purpose of estimating baseline emissions, EPA assumed that surface impoundments would either be converted to open-top tanks or, for certain treatment impoundments, would be dredged annually to comply with the LDR. Because surface impoundments and open-top tanks have similar air emission mechanisms, EPA assumed that baseline emissions for surface impoundments would be the same as current emissions.

3. Containers

Another TSDF organic emission source is the release of organics from the storage of waste in containers that are not tightly closed and during the transfer of waste into the containers. Containers include drums, tank trucks, railroad tank cars, and dumpsters. Although existing RCRA regulations requiring containers to be closed during storage (Subpart I in 40 CFR 264 and 265) help reduce organic emissions, organic emissions will occur from gaps between the container lip and the cover unless a tight-fitting cover is used. Emissions during container loading operations occur when liquid or sludge wastes are poured into a container, displacing an equal volume of air that is saturated or nearly saturated with organics from inside the container to the ambient air. Current organic emissions associated with the transfer and storage of waste in containers are estimated to be approximately 85,000 Mg/yr. Because additional controls will not be applied to TSDF containers as result of existing RCRA rules, this emission estimate is also assumed to represent emissions at baseline.

4. Waste Fixation

As a result of LDR, certain liquid, slurry, and sludge hazardous wastes are now treated at TSDF using a waste fixation process (also referred to as waste solidification or stabilization) so that the waste can be placed in a hazardous waste landfill. The term "waste fixation," as used in this preamble, refers to a chemical process in which the free water in the waste reacts with a binder (commonly cement kiln or lime kiln dust) to form a solid material that immobilizes specific metal and organic contaminants in the waste.

Waste fixation involves first mixing the waste with the binder material. The simplest mixing procedure used at TSDF involves dumping the waste into an open-top tank, surface impoundment, waste pile, or dumpster; adding the binder to the waste; and mixing the materials together using a backhoe or other construction machinery. A similar procedure is used but on a smaller scale for fixating waste directly in drums. At some TSDF, open mixing of the waste and binder has been replaced by the use of enclosed mechanical mixing devices such as a pug mill or a ribbon blender. Following mixing, the mixture is cured by holding the mixture for a sufficient period of time (usually 24 to 48 hours) to allow the mixture to harden. The waste is then tested, and if it meets the appropriate treatment standards, the waste is placed in a landfill.

Organic emissions from waste fixation occur when organics in the waste volatilize and are released to the atmosphere during mixing and curing. Current emissions from waste fixation operations are estimated at approximately 2,000 Mg/yr. Baseline emissions are estimated to increase significantly above the current level because of the assumption that the TSDF industry will respond to the LDR by using waste fixation to convert dilute aqueous liquids, aqueous sludges/slurries and high-solids content waste mixtures into solid materials that can be placed in a landfill. Baseline emissions from waste fixation are estimated to increase to approximately 180,000 Mg/yr.

5. Land Treatment Units

Land treatment involves treating the waste by spreading a waste on top of or injecting it into the soil, and then tilling the soil for the purpose of allowing soil bacteria to decompose organic material and fixing the metals in the soil matrix. A waste may be dewatered to lower its water content before being applied to the soil. Organic emissions are generated from land treatment operations during application, tilling, and decomposing, both from direct volatilization of organics that are land treated and from volatile organics that are formed during the decomposition of heavy organics. If a dewatering device is used, emissions may also occur from this device, for example, from the vacuum pump exhaust (on vacuum filters), as well as from the filter cake collection system. However, the major emission source is the soil surface in the land treatment operation itself. Current emissions from land treatment operations are estimated at approximately 73,000 Mg/yr. Baseline emissions from land treatment are estimated to be reduced to zero assuming that in response to LDR: (1) All wastes currently land treated with the exception of high-solids content

waste mixtures will instead be incinerated, and (2) the high-solids content waste mixtures will be treated by waste fixation and then landfilled.

6. Landfills

A hazardous waste landfill generally is an excavated, lined pit into which wastes are placed for permanent disposal. Emissions can occur from both active and closed landfill facilities. Only emissions from active landfills were estimated by the national impacts model. Although EPA continues to evaluate emissions from closed landfills, emissions from these sources are difficult to estimate because of the need for information related to the waste types and quantities as well as when the waste was buried at the site. In an active landfill, whether open or covered with earth, the landfill surface is the major emission point. Emissions occur from the landfill surface as a result of the evaporation of organics and the diffusion of the vapors up to the landfill surface and into the air. Other activities generating emissions at an active site include waste transport, unloading, and spreading. Current nationwide organic emissions from active landfills are estimated at approximately 40,000 Mg/yr. Although the amount of waste landfilled after implementation of the LDR is estimated to increase over current levels due to increased waste fixation, emissions are estimated to be substantially reduced because of the assumptions that: (1) The LDR treatment standards will require that the fixated wastes contain no free organics, and (2) all organic liquid and organic sludge/slurry wastes currently placed in landfills will instead be incinerated in response to the LDR. Baseline emissions from active landfills are estimated to be approximately 2,100 Mg/yr.

7. Waste Piles

A waste pile is used for the short-term storage of wastes. As with landfills, organic emissions can be released due to volatilization from the waste pile surface. The EPA estimated that current emissions from waste piles are approximately 130 Mg/yr. For baseline, it is assumed that all organic liquid and organic sludge/slurry wastes currently placed in waste piles will instead be incinerated in response to the LDR. Baseline emissions from waste piles are estimated to be approximately 33 Mg/yr.

8. Hazardous Waste Incinerators

Organic emissions are released from the exhaust stacks of hazardous waste incinerators as well as boilers and industrial furnaces used to burn hazardous waste. Current emissions from hazardous waste incinerators are estimated to be 880 Mg/yr. For baseline it is assumed that increased quantities of waste will be incinerated in response to the LDR. Organic emissions from hazardous waste incinerators are regulated by RCRA standards in 40 CFR 264 subpart O, and air emissions from boilers and industrial furnaces burning hazardous waste are regulated under recently promulgated RCRA standards (56 FR 7134, February 21, 1991). At baseline, organic emissions from the incineration of hazardous wastes are estimated to increase to a level of approximately 1,100 Mg/yr.

9. Treatment Unit Process Vents

Organic emissions are also released from the process vents of distillation, fractionation, evaporation, solvent extraction, air stripping, and steam stripping units used to treat hazardous wastes containing volatile organics. Current organic emissions from these sources are estimated to be approximately 8,100 Mg/yr. Air emission standards for process vents (Subpart AA in 40 CFR parts 264 and 265) are in effect and are estimated to reduce process vent emissions to approximately 900 Mg/yr at baseline.

10. TSDF Equipment leaks

Emissions from equipment leaks occur when waste leaks from seals, gaskets, sampling connections or other openings in waste handling processes. Equipment leak emissions from TSDF handling waste having an organic content of 10 percent or more are estimated at approximately 26,200 Mg/yr. Air emission standards for equipment leaks (Subpart BB in 40 CFR parts 264 and 265) are in effect and are estimated to reduce these organic emissions to approximately 7,200 Mg/yr at baseline.

D. Particulate Matter Emissions

The EPA conducted a study to determine the magnitude of fugitive emissions of contaminated particulate matter from TSDF and to determine if these emissions pose a threat to human health or the environment. Fugitive emission sources of contaminated particulate matter identified included active landfills, dry surface impoundments, waste storage piles, land treatment areas for liquid wastes, and stabilization or solidification areas for liquid wastes. Eight TSDF were surveyed and sampled to assess the potential magnitude of particulate emissions, the degree of contamination of the particulate matter, and the health risks posed by these emissions. The results of these site surveys were scaled up to assess nationwide impacts. The conclusion of this assessment was that there is no major nationwide health problem associated with TSDF particulate emissions but that there is the potential for site-specific problems. Consequently, rather than developing additional nationwide standards, EPA has developed a technical guidance document (EPA publication no. 450/3-89-019) to supplement existing particulate standards which can be used to identify and correct site-specific health problems associated with fugitive particulate matter emissions. While EPA believes that this approach to fugitive emissions is appropriate, but because there may be alternative approaches that EPA has not considered, the public is requested to comment on the appropriateness and effectiveness of the selected approach.

E. Selection of Sources for Control

The EPA's objective in selecting TSDF organic emission sources for control by today's proposed standards is to control the major TSDF air emission sources that are not already addressed, either directly or indirectly, by other RCRA standards. Table 1 presents a summary of the nationwide TSDF organic emission estimates by emission source type.

TABLE 1.—NATIONWIDE TSDF ORGANIC EMISSIONS ESTIMATES

Emission Source Type	Number of TSDF with source type	Nationwide organic emissions (thousand Mg/yr)	
		Current	Baseline
Tanks [a]			
Storage and quiescent treatment	911	800	810
Nonquiescent treatment	291	440	440

TABLE 1.—NATIONWIDE TSDF ORGANIC EMISSIONS ESTIMATES—Continued

Emission Source Type	Number of TSDF with source type	Nationwide organic emissions (thousand Mg/yr)	
		Current	Baseline
Surface Impoundments:			
Storage and quiescent treatment	270	210	210
Nonquiescent treatment	127	74	74
Containers [b]	1,440	85	85
Waste Fixation [c]	158	2	180
Land Treatment Units	54	73	0 [d]
Landfills	90	40	2 [d]
Waste Piles	57	<1	<1 [d]
Hazardous Waste Incinerators	158	1	1 [e]
Treatment Unit Process Vents [f]	450	8	1 [e]
TSDF Equipment Leaks	1,440	26	7 [e]
TOTAL		1,760	1,811

[a] Estimates do not include generator accumulation tanks.
[b] Estimates do not include generator accumulation containers.
[c] Waste solidification process involving the mixing of a waste and a binder in a tank, surface impoundment, container, or other type of hazardous waste management unit.
[d] Baseline estimate assumes waste will be treated to remove or destroy organics prior to placement in the unit to comply with land disposal restrictions.
[e] Organic emissions regulated by existing RCRA standards.
[f] Distillation, fractionation, evaporation, solvent extraction, air stripping, and steam stripping waste treatment processes.

Total nationwide organic emissions from TSDF at baseline are estimated to be approximately 1.8 million Mg/yr. These emissions represent approximately 12 percent of total nationwide, stationary source emissions of organic compounds. The emission estimates presented in Table 1 indicate that at baseline the major TSDF organic emission sources will be tanks, surface impoundments, containers, and waste fixation operations. On the basis of these nationwide organic emission estimates, EPA selected TSDF tanks, surface impoundments, and containers for control by today's proposed standards. Because waste fixation is commonly performed in tanks, surface impoundments, and containers, controlling these units would also reduce organic emissions from waste fixation operations. Also, as discussed in Section VIII, EPA selected for control by today's proposed standards certain tanks and containers used by hazardous waste generators to accumulate waste on-site for short periods of time.

The EPA did not select land treatment, landfills, or waste piles for control by today's proposed standards. The LDR (refer to Section II) require treatment of certain hazardous wastes to reduce the toxicity or mobility of specific waste constituents before the waste can be placed in a land disposal unit. Because LDR are generally performance standards that can be complied with using one of several methods and many are not yet promulgated, it was necessary for EPA to make certain assumptions about how the TSDF industry will respond to LDR. The EPA assumed that LDR will require the organics in the waste to be removed or destroyed prior to placement in a land treatment unit, landfill, or waste pile resulting in the low organic emission levels shown in Table 1. Based on this analysis, EPA concluded that additional control requirements for air emissions from land treatment units, landfills, and waste piles should not be proposed at this time. As more LDR are promulgated and the protectiveness of the LDR with respect to TSDF air emissions can be better assessed, EPA will review this decision and, if necessary, develop additional air emission standards for land disposal units.

As discussed in section II, EPA has already promulgated air emission standards under RCRA to control organic emissions from certain types of hazardous waste treatment processes including hazardous waste incinerators, nonthermal destruction treatment unit process vents, and TSDF equipment leaks. The baseline organic emissions from these sources as shown in Table 1 will be very low. Subpart O in 40 CFR Part 264 establishes organic emission performance standards for hazardous waste incinerators and other thermal destruction treatment processes. Subpart AA in 40 CFR part 264 sets organic emission performance standards applicable to distillation, fractionation, evaporation, solvent extraction, air stripping, and steam stripping waste treatment processes. Subpart BB in 40 CFR part 264 regulates organic emissions resulting from leaks associated with certain types of equipment used for hazardous waste management units. For these reasons, additional standards are not proposed for these sources.

IV. Emission Controls

A. Selection of Emission Controls

The EPA identified several emission control technology approaches that can be used to reduce organic emissions from hazardous waste tanks, surface impoundments, and containers. These include: (1) Containment and control of the organic emissions released from the waste as it is managed in tanks, surface impoundments, and containers; and (2) pretreatment of the waste to remove or destroy the organics in the waste prior to placement of the waste in tanks, surface impoundments, or containers.

Containment and control of the organic emissions released from the waste involve the application of add-on emission controls to individual tanks, surface impoundments, and containers. Organic vapors can be suppressed by applying a cover that directly contacts the waste medium, thereby creating a physical barrier at the waste surface which inhibits the volatilization of organics. However, the potential remains that the volatile organics retained in the waste could ultimately be released to the atmosphere from a point further downstream in the management of the waste unless other emission control measures are used in conjunction with the covers. Another method for containing the volatile organics is to form a closed vapor space above the waste surface by erecting an enclosure over the entire waste management unit or, for some types of open-top units, installing a cover. Whe this containment method is used in combination with a closed vent system and a control device (e.g., carbon

adsorbers, vapor incinerators, condensers), organic vapors released from the waste and contained in the vapor space are captured and treated (i.e., removed or destroyed).

Pretreatment of the hazardous waste removes or destroys organics in the waste and, thus, reduces organic emissions from all subsequent waste management units handling waste without the need to use add-on emission controls for each of these units. For example, if a waste is pretreated by steam stripping to remove organics, the quantity of organic emissions from all activities that subsequently manage the waste will be reduced relative to the quantity of emissions that would have occurred without pretreatment because of the reduction in the volatile organic content of the waste. Similarly, if a waste is incinerated then there are no additional waste handling steps (other than the disposal of ash and other noncombustible residuals remaining after the waste is incinerated), and thus there are no subsequent waste management units that are sources of organic emissions.

To select the emission control technologies to be further evaluated for the development of organic emission standards for hazardous waste tanks, surface impoundments, and containers, EPA considered the possible fates of waste placed in these units. All hazardous waste ultimately is either recycled as a product, treated for disposal, land disposed, or discharged to a wastewater disposal system. The EPA evaluated the suitability of using an organic emission containment and control approach (i.e., application of covers and enclosures with, where appropriate, control devices) for hazardous waste tanks, surface impoundments, and containers with respect to how other EPA rulemakings would impact overall organic emissions from the activities that ultimately may be used to manage a waste.

For wastes that are eventually recycled as products (e.g., organic solvents, fuel), containment and control of the volatile organics released from waste while it is managed in tanks, surface impoundments, and containers prior to being recycled would be suitable since the organics are reused. As discussed in Sections II and III, organic emissions from waste that ultimately is treated and disposed or is land disposed are impacted by existing standards under RCRA regulating organic emissions from certain hazardous waste treatment processes, and by the ongoing development of the LDR. The EPA is assuming that these standards will require waste be managed in such a manner that the organics in the waste are destroyed or removed by treatment units controlled for organic emissions prior to disposal. Therefore, based on this assumption, use of organic emission containment and control for hazardous waste tanks, surface impoundments, and containers would also be suitable for waste that is ultimately treated and disposed, or land disposed.

Using an organic emission containment and control approach for waste that is managed in tanks, surface impoundments, and containers, and then discharged to a wastewater treatment system may not be suitable without other regulatory requirements. Other EPA control programs are being implemented or are in development (e.g., prevention of significant deterioration (PSD) and new source review requirements, publication of control technique guidelines (CTG), new rulemakings under the Clean Air Act) which will affect the discharge of certain hazardous wastes which contain volatile organics by establishing discharge standards for these wastes or air emission standards for wastewater treatment units used to treat the waste. Therefore, eventually, if not already, hazardous waste managed in tanks, surface impoundments, and containers, and then discharged to a wastewater treatment system, will be affected by other regulatory requirements. For today's proposal, EPA is assuming that the control equipment required by these other EPA control programs when implemented will result in waste being managed in such a manner that the organics in the waste are destroyed or removed by treatment units controlled for organic emissions prior to discharge to a wastewater treatment system. Based on this assumption, use of organic emission containment and control for hazardous waste tanks, surface impoundments, and containers would also be suitable for waste that is ultimately discharged as wastewater.

Based on the key assumptions described above, EPA concluded that organic emission containment and control in combination with the other EPA rulemakings will provide an integrated approach to reducing organic emissions from TSDF tanks, surface impoundments, and containers. Once more LDR and organic emission control requirements affecting wastewater discharge are promulgated and the protectiveness of these standards with respect to organic emissions can be better assessed, EPA will review the assumptions used as the basis for selecting organic emission containment and control as the emission control technology approach for hazardous waste tanks, surface impoundments, and containers. If these assumptions are no longer valid and additional standards are found to be necessary under section 3004 of RCRA to protect human health and the environment, then EPA will investigate alternative emission control technology approaches that can be used to reduce organic emissions from TSDF tanks, surface impoundments, and containers.

B. Covers and Enclosures

Covers or enclosures reduce organic emissions by suppressing the generation and loss of vapors containing the organics. Appropriate types of covers include fixed roofs, internal floating roofs, and external floating roofs for tanks; covers for containers; and floating synthetic membranes for surface impoundments. Enclosures are structures erected over the entire waste management unit such as an air-supported structure over a surface impoundment or an enclosed building over a drum handling and storage area. However, enclosures are not suitable for organic emissions control without being vented through a control device because air must be continuously or periodically vented from an air-supported structure or enclosed building to maintain organic vapor concentrations inside the structure below lower explosive limits.

A fixed roof is a rigid cover that typically is equipped with pressure/vacuum vents to allow the tank to operate at a slight positive pressure. Fixed roofs are applicable for controlling emissions from storage tanks and certain types of treatment tanks, and can reduce emissions by 86 to 99 percent depending on the volatility and concentration of organics in the waste. Fixed roofs may also be used for emission controls on mixed or aerated tanks. For these sources, large dome-shaped roofs would be used to allow room for operation of surface-mounted aerators or agitators. However, for tanks in which mixed or aerated processes are conducted, fixed roofs would not be an effective emission control without the addition of a closed vent system and control device.

External floating roofs are rigid covers that float on top of the waste in a tank. A flexible seal is installed along the roof rim to control volatilization of organics from the space between the roof deck and the tank wall. These roofs are applicable to certain storage or treatment tanks and are capable of reducing emissions by 93 to 97 percent

relative to open tanks. External floating roofs may not be appropriate for tanks storing certain corrosive or solvent wastes because of potential incompatibilities between the waste and the roof seal. This type of roof also is not appropriate for treatment tanks requiring the use of equipment placed on or above the waste surface.

Internal floating roofs are similar to external floating roofs except that internal floating roofs are used in conjunction with a fixed roof. These roofs can be applied to tanks that already have a fixed roof or can be applied along with a fixed roof to uncovered tanks. The control efficiency of internal floating roofs used in conjunction with fixed roofs is estimated to range from about 93 percent to 97 percent relative to fixed roof tanks. As with external floating roofs, internal floating roofs may not be applicable to tanks containing certain corrosive or solvent wastes because of potential incompatibilities between the waste and the roof seal.

Similar to using a fixed roof tank to manage hazardous waste, placing a cover over a surface impoundment reduces the release of volatile organics contained in the waste by preventing waste mixing due to wind blowing across the unit. One type of cover available for application to surface impoundments is a floating membrane cover. A floating membrane cover consists of large sheets of synthetic, flexible membrane material that float on the surface of a liquid or sludge. Individual, standard dimension sheets can be seamed or welded together to form covers applicable to any size surface impoundment. Floating membrane covers have been used for many years to cover the surface of potable water reservoirs. More recently, use of floating membrane covers has been extended to applications that require the cover to be airtight such as covering anaerobic sludge lagoons.

The effectiveness of using a floating membrane cover for organic emission control is a function of the amount of leakage from the cover fittings and seams as well as the losses resulting from the permeation of the membrane material by volatile organic compounds contained in the waste. The successful application of floating membrane covers to anaerobic sludge impoundments demonstrates that leakage from fittings and seams can be reduced to very low levels by using a membrane material with adequate thickness, installing proper seals on cover fittings and vents, and following good installation practices to ensure that the seams are properly welded and to prevent tearing or puncturing the membrane material. Consequently, for a properly installed floating membrane cover, the organic emission control effectiveness is expected to be primarily determined by the permeability of the cover to the organic constituents in the waste.

Permeability is a measure of resistance of a membrane material to the organics passing through the membrane. Permeation of a membrane material is a three-step process that involves the adsorption of the organics by the material, diffusion of the organics through the material, and evaporation of the organics on the air side of the membrane. The permeability of a floating membrane cover is a function of the organic composition and concentration of the waste managed in the surface impoundment as well as the cover material composition and thickness.

No source test data are available to measure the effectiveness of a floating membrane cover in controlling organic emissions from a surface impoundment. However, the effectiveness of using floating membrane covers applied to representative TSDF surface impoundments has been estimated using experimental test data and theoretical mass transfer relationships. These estimates suggest that a flexible membrane cover fabricated from high density polyethylene (HOPE) can be an effective organic emission control for hazardous waste managed in TSDF surface impoundments. For example, the organic emission control levels estimated for a 2.5 mm HDPE floating membrane cover range from approximately 50 percent to over 95 percent depending on the organic constituents in the waste and the waste retention time in the surface impoundment.

For surface impoundment applications where installation of a floating membrane cover is not possible, such as a treatment surface impoundment using surface aerators, the impoundment could be covered with an air-supported structure. An air-supported structure is a plastic-reinforced fabric shell that is inflated and, therefore, requires no internal rigid supports. Large fans are used to blow air continuously or intermittently through the structure and out a vent system. The vent system can discharge directly to the atmosphere or be connected to an add-on control device. Not venting the enclosure to a control device would make the air-supported structure useless for organics emission control.

The effectiveness of an air-supported structure in controlling organic emissions depends on the the amount of leakage from the structure and the efficiency of the control device. Operating experience with air-supported structures has shown that with proper installation and maintenance, leakage can be limited to very low levels. Thus, the overall organic emission control efficiency for TSDF applications using an air-supported structure would be approximately equivalent to the efficiency of the control device used. Large areas can be enclosed by air-supported structures and, thus, would be suitable for use at TSDF area sources such as surface impoundments.

Rigid enclosures, much like conventional buildings, may be constructed of metal or other materials and would be appropriate for enclosing waste management operations such as surface impoundments or container storage areas. Rigid enclosures reduce emissions by reducing the mixing effects of wind and heating effects of sunlight on the organic volatilization rate for waste placed in the unit enclosed by the structure.

C. Submerged Loading

Submerged loading is a work practice that reduces emissions during container loading. During loading of liquid waste into containers, if the fill pipe is lowered only partially into the container, waste flows from the end of the pipe that is above the liquid level in the container, and significant turbulence and vapor-liquid contact occur when the falling liquid splashes on the surface of the liquid already in the container. This technique is referred to as splash loading and results in organic vapor generation and emissions to the atmosphere through the container opening used for waste loading. The induced turbulence, evaporation, and liquid entrainment is substantially reduced by the use of submerged loading in which the end of the fill pipe is positioned below the liquid surface of the waste in the container. This control technique is applicable to the loading of liquid wastes and many sludges into containers of all types. It is estimated to reduce emissions from TSDF container-loading operations by approximately 65 percent relative to splash loading.

D. Control Devices

1. Use of Closed Vent System with Control Device

A variety of control devices are available that are capable of achieving high organic emission control

efficiencies. Organic removal control devices extract the organics from the gas stream and recover the organics for potential recycling or reuse. Organic destruction control devices destroy the organics in the gas stream by oxidation of the organic compounds, primarily to carbon dioxide (CO_2) and water. The type of control device best suited for reducing emissions from a particular covered or enclosed waste management unit depends on the size of the unit and the characteristics of the organic vapor stream vented from the unit.

To achieve the maximum potential control device organic emission reduction efficiency, the vent system used to convey the organic vapors from the covered or enclosed waste management unit to a control device must be closed so that no organic vapors can escape directly to the atmosphere prior to the vapor stream entering the control device. A closed vent system consists of piping, connections and, in some cases, a flow inducing device (e.g., a fan or blower) to transport the vapor stream.

2. Organic Removal Control Devices

Adsorption, condensation, or absorption processes can be used to extract the organics from a gas stream. Considering organic vapor stream characteristics, the organic removal control devices most likely to be used for TSDF waste management units are carbon adsorbers and condensers.

Carbon adsorption is the process by which organic molecules in a gas stream are retained on the surface of carbon particles. The gas stream is passed through a bed of carbon particles that have been processed or "activated" to have a very porous structure. However, activated carbon has a finite capacity for adsorbing the organics. When the carbon becomes saturated (i.e., all of the carbon surface is covered with organic material), there is no further organic emission control because all of the organic vapors pass through the carbon bed. At this point, the adsorbed organics must be either regenerated (i.e., the organics desorbed from the carbon surface) or the spent carbon replaced with fresh carbon before organic emission control can resume.

Two types of carbon adsorption systems most frequently used for organic emission control are fixed-bed carbon adsorbers and carbon canisters. Fixed-bed carbon adsorbers are used for controlling organic vapor streams with flow rates ranging from 30 to over 3,000 m^3/min (1,000 to over 100,000 ft^3/min). When the carbon becomes saturated, the carbon is regenerated directly in the bed by passing steam through the carbon bed. The steam heats the carbon particles, which releases the organic molecules into the steam flow. The resulting steam and organic mixture is condensed to recover the organics and separate the water for discharge to a wastewater treatment unit. Because most waste management units vent organic vapors 24 hours per day, fixed-bed carbon adsorber systems would need to be used with two or more carbon beds so that at least one bed is always available for adsorption while other beds are being regenerated.

In contrast to a fixed-bed carbon adsorber, a carbon canister is a very simple device consisting of a drum filled with activated carbon and fitted with inlet and outlet pipes. Use of carbon canisters is limited to controlling organic emissions from TSDF waste management units venting vapor streams with intermittent or low continuous flow rates such as storage tanks or quiescent treatment tanks. Once the carbon becomes saturated by the organic vapors, the spent carbon canister must be removed and replaced with a fresh carbon canister. The spent carbon is then returned to a carbon vendor for regeneration or disposal depending on site-specific factors.

The design of a carbon adsorption system depends on the inlet gas stream characteristics including organic composition and concentrations, flow rate, and temperature. Good carbon adsorber performance requires that: (1) The adsorber is charged with an adequate quantity of high-quality activated carbon; (2) the gas stream receives appropriate preconditioning (e.g., cooling, filtering) before entering the carbon bed; and (3) the carbon beds are regenerated before breakthrough occurs (i.e., before the carbon becomes saturated). Emission test data for full-sized, fixed-bed carbon adsorbers operating in industrial applications have been compiled by EPA. Analysis of these data indicates that for well-designed and well-operated carbon adsorbers, continuous organic removal efficiencies of at least 95 percent are achievable over long periods.

For carbon adsorption systems requiring steam to regenerate spent carbon, secondary air emission impacts could result if the steam is produced in a direct-fired boiler. These emissions include carbon monoxide (CO) and nitrogen oxides (NO_x), as well as possibly sulfur oxides (SO_x) and particulate matter if oil or coal is burned in the boiler. Spent carbon which no longer is suitable for use in carbon adsorption systems and cannot be regenerated must be disposed as a solid waste. The quantities of solid waste and secondary air emissions generated are small relative to the reduction in organic emissions.

Condensers convert organic gases or vapors to liquid form by lowering the temperature or increasing the pressure. For TSDF organic emission control applications, surface condensers are most likely to be used. Surface condensers most often consist of a shell-and-tube-type heat exchanger. The organic vapor stream flows into a cylindrical shell and condenses on the outer surface of tubes that are chilled by a coolant flowing inside the tubes. The coolant used depends on the saturation temperature or dewpoint of the particular organic compounds in the gas stream. The condensed organic liquids are pumped to a tank for recycling or reuse.

The performance of a condenser is dependent upon the gas stream organic composition and concentrations as well as the condenser operating temperature. Condensation can be an effective control device for gas streams having high concentrations of organic compounds with high-boiling points. However, condensation is not effective for gas streams containing low organic concentrations or composed primarily of low-boiling point organics because the organics cannot be readily condensed at normal condenser operating temperatures. For example, data from a condenser field test indicate an organic removal efficiency over 99 percent for 1,2-dichloroethane (high boiling point organic), but an organic removal efficiency of only 6 percent for vinyl chloride (low boiling point organic). Use of surface condensers for TSDF organic emissions would produce no cross-media or secondary air emission impacts other than any impacts attributed to the generation of electricity needed to power the equipment.

2. Organic Destruction Control Devices

Organic destruction control devices include thermal vapor incinerators, catalytic incinerators, flares, boilers, or process heaters. Because of applicability restrictions, a particular type of combustion device may not be suitable for controlling certain organic vapor streams vented from covered or enclosed TSDF waste management units.

Thermal vapor incineration is a controlled oxidation process that occurs in an enclosed chamber. The organic destruction efficiency for a thermal vapor incinerator is primarily a function of combustion zone temperature, the period of time the organics remain in the combustion zone (i.e., residence time),

and the degree of turbulent mixing in the combustion zone. When designed and operated to achieve the proper mix of combustion zone temperature, residence time, and turbulence, thermal vapor incinerators can achieve organic destruction efficiencies of 98 percent and higher for all types of organic vapor streams.

The performance of a thermal vapor incinerator is affected by the heating value of the organic vapor stream to be controlled. Concentrated organic vapor streams normally have sufficient heating value to sustain combustion. However, dilute organic vapor streams such as can be vented from TSDF storage and quiescent treatment tanks used to manage dilute aqueous waste have low heating values. Consequently, the continuous addition of a supplemental fuel (e.g., natural gas or fuel oil) to boost the heating value of these vapor streams is required in order to maintain combustion zone temperatures in the range necessary for 98 percent organic destruction efficiency. Supplemental fuel may also be necessary for incinerating variable organic vapor streams in order to maintain flame stability. Thus, use of thermal vapor incinerators to control dilute or variable organic vapor streams may require substantial fuel consumption.

Using good thermal vapor incinerator design and operating practices limit CO emissions to very low levels. However, the combustion temperature levels required to achieve good organic vapor destruction efficiency also results in the formation of NO_x. Emission source test data indicate that NO_x emissions from thermal vapor incinerators are very low for concentrated organic vapor streams that do not require the addition of large quantities of supplemental fuel. The need to continuously add supplemental fuel in order to incinerate dilute organic vapor streams may increase NO_x emissions to levels associated with industrial boilers or process heaters burning similar quantities of the same fuel. If compounds containing chlorine are present in the organic vapor stream, hydrogen chloride will be formed when the vapors are incinerated. Similarly, the presence of sulfur compounds in the vapor stream results in the formation of SO_x Although not addressed by this rulemaking, both HCl and SO_x emissions can be controlled by venting the incinerator exhaust gases through a wet scrubber. The scrubber effluent would increase the total TSDF wastewater to be handled by wastewater treatment units.

Catalytic vapor incineration is essentially a flameless combustion process that can be used to control certain types of organic vapor streams. The organic vapor stream is passed through a metal or alloy-based catalyst bed that promotes organic oxidation reactions at temperatures in the range of 320 to 360 °C (600 to 1,200 °F). Temperatures below this range slow down or stop the oxidation reactions. Consequently, the organic vapor stream from the emission source is first preheated by passing the organic vapors through a heat exchanger and, if necessary, mixing the organic vapors with hot combustion gases from auxiliary burners fired using natural gas. Catalytic incinerator organic destruction efficiencies of 98 percent or more can be obtained by using the appropriate catalyst bed volume to gas flow rate for certain organic vapor streams.

The applicability of catalytic incineration to controlling organic vapor streams is restricted to fewer organic vapor stream compositions and concentrations than can be controlled by thermal vapor incinerators. The incinerator catalysts are very susceptible to rapid deactivation by halogens or sulfur. Thus, catalytic vapor incineration is not suitable for organic vapor streams containing halogen or sulfur compounds. Also, oxidation of vapor streams with high organic contents can produce high temperatures that shorten catalyst life or may even cause catalyst failure. Consequently, certain concentrated organic vapor streams may not be suitable for catalytic incineration.

In general, catalytic vapor incinerators have neither the NO_x air emission impacts nor the potential HCL and SO_x air emission impacts associated with thermal vapor incinerators because of the lower operating temperatures and the applicability restrictions. If auxiliary burners are required to preheat the organic vapor stream, small quantities of NO_x may be emitted from the auxiliary burner flame zone. Because the incinerator catalyst must be periodically replaced with fresh catalyst, the spent catalyst is either returned to a catalyst vendor for recycling or disposed as a solid waste.

Unlike vapor incinerators, flares are open combustion devices. The ambient air surrounding the flare provides the oxygen needed for combustion. A natural-gas-fired pilot burner ignites the organic vapor stream. Steam- or air-assisted flares can achieve an organic destruction efficiency of at least 98 percent on organic vapor streams having a heat content greater than 11 megajoules per cubic meter (300 Btu/ft^3) when designed and operated according to EPA's guidelines specified in 40 CFR 60.18. Flares are not suitable for use on organic vapor streams that contain halogens or sulfur compounds because the acid gases formed from these compounds during combustion cause severe corrosion and excess wear of the flare tips. Emission source test results indicate that NO_x emissions from flares are very low for concentrated organic vapor streams that do not require the addition of large quantities of supplemental fuel.

An existing industrial boiler or process heater can also be used for organic vapor destruction. The organic vapor stream is either premixed with a gaseous fuel and fired using the existing burner configuration, or fired separately through a special burner or burners that are retrofitted to the combustion unit. Studies of burning hazardous organic waste vapors in industrial boilers and process heaters indicate organic destruction efficiencies of 98 percent or more. Because a boiler or process heater normally is already firing natural gas or other fuel to provide steam or heat for a manufacturing process, using an existing boiler or process heater may allow organic vapor streams with lower heating values to be burned without the need to use additional fuel. However, because plant operations require these combustion units to be on-line for long periods of time, industrial boilers and process heaters are suitable for controlling only organic vapor streams that do not impair the combustion device performance (e.g., reduce steam output) or reliability (e.g, cause premature boiler tube failure).

V. Development of standards for organic emissions

A. Development of Control Options

1. Control Option Concept

The objective of today's proposed standards is to reduce organic emissions from TSDF tanks, surface impoundments, and containers that manage hazardous wastes. The total quantity of organic emissions reduced nationwide by implementing standards for these TSDF units is a function of which hazardous wastes are selected to be regulated, which TSDF units managing these wastes use emission controls, and the degree of organic emission reduction that the emission controls achieve. To select a basis for the proposed standards, EPA identified and evaluated a variety of possible strategies for applying the emission controls selected in Section IV to TSDF tanks, surface impoundments, and containers. Each strategy considered by

EPA is referred to as a "control option." Different control options were identified by varying the types of waste management units that would need to use emission controls and the level of organic emission reduction that would be required for the emission controls.

Each control option defines a unique set of wastes (based on volatile organic concentration) and organic emission control levels that are used by EPA to perform an impact analysis using the national impacts model described in Section III. This analysis provides estimates of the nationwide human health and environmental impacts expected to occur if standards based on a particular control option were promulgated. The EPA compared the control option impacts relative to a common set of reference values called the "baseline." The baseline represents the estimated human health and environmental impacts that would occur in the absence of implementing any of the control options. For the control option impact comparison, a baseline was chosen to reflect the impacts of other RCRA and Clean Air Act regulations affecting organic emissions from TSDF tanks, surface impoundments, and containers that will have been implemented by the date when any standards being developed under this rulemaking are expected to be promulgated.

Hundreds of possible control options can be identified for the various combinations of hazardous wastes and emission control levels. However, performing an impact analysis for every possible control option regardless of the control option's potential to protect human health and the environment would be a very time-consuming task and require extensive expenditure of EPA resources. Therefore, EPA first conducted a screening evaluation to narrow the number of control options for the impact analysis. This evaluation is available in the docket. The evaluation results were used to define a subset of appropriate control options from which the basis for the proposed standards could be selected.

2. Action Levels Considered for Control Options

The need to apply emission controls to a particular TSDF tank, surface impoundment, or container can be determined by the potential emissions from a particular hazardous waste managed in the unit. Indicators of potential emissions are referred to here as "action levels." Owners and operators of TSDF units with emission levels equal to or greater than a specified action level would be required to initiate "action" by installing and using certain emission controls. In contrast, owners and operators of TSDF units with emission levels less than this action level would not be required to use emission controls. However, these owners and operators would be required to perform periodic waste determinations to ensure the TSDF unit's emission level remains below the action level.

As is discussed in Section IV, EPA selected an emission containment and control approach to reduce organic emissions from hazardous waste tanks, surface impoundments, and containers. To implement this approach using an action level, the same action level can be applied throughout the entire waste management process or different action levels can be applied at individual stages of the waste management process. The EPA decided to use a single action level from the point of waste generation through the point where the organics in the waste are either recycled, removed, or destroyed. The reasons are discussed below.

When only a cover is applied to a tank, surface impoundment, or container, the volatilization of the organics in the waste is inhibited, but the organics are generally neither removed or destroyed. When a cover vented to a control device is applied to a tank, surface impoundment, or container, a portion of the organics in the waste are emitted from the waste stream and vented to the control device. Organics still remain in the waste and can potentially be emitted from subsequent waste management units located downstream of the controlled waste management unit. However, when a tank, surface impoundment, or container is covered and the waste in the unit is agitated or aerated, a high proportion of the organics may be emitted and vented to a control device. Nevertheless, the remaining organics can potentially be vented from downstream waste management units. Therefore, using a higher action level for downstream waste management units than is used for the upstream waste management units reduces the overall effectiveness of the organic emission containment and control approach. A higher action level would allow some portion of the organics remaining in the waste to be emitted from the uncontrolled downstream units.

Approximately two-thirds of the baseline emissions are estimated to occur from quiescent tanks and quiescent surface impoundments (i.e., the waste managed in the unit is neither aerated nor agitated). If the waste stream is not agitated or treated upstream of these units, the application of controls on the upstream units would serve to primarily shift the point where the organic emissions occur instead of reducing organic emissions. This rationale led EPA to propose a single action level from the point of waste generation through the point where the organics in the waste are either recycled, removed, or destroyed. The EPA is requesting comment on the effect of using different action levels on certain downstream units (e.g., those used for waste fixation) versus applying the same action level through the entire waste management process.

One direct way to set an action level for a particular emission source is in terms of an emission level or rate that expresses the quantity of organics emitted over time (e.g., kilograms of organics per hour, megagrams of organics per year). This format is well-suited for those organic emission sources where the pollutant gas stream is emitted from a single point where it can be readily measured such as the exhaust stack from a boiler or the vent stack from a chemical process unit.

Unfortunately, using an emission rate format to establish the action level for many TSDF tanks, surface impoundments, and containers is not practical because of the air emission mechanism, design configuration, and operating practices used for these units. At existing TSDF, hazardous waste is often managed in tanks, surface impoundments, and containers that are not covered. Because the entire waste surface is open to the atmosphere, organic emissions occur across large areas. Consequently, to measure the actual quantity of emissions from the unit, a gas-tight enclosure would need to be erected temporarily over the entire TSDF unit's exposed waste surface to capture all organic emissions. Thus, actual measurement of the organic emissions from an uncovered TSDF unit would be an impractical and expensive means for a TSDF owner or operator to use periodically for determining if a unit's emissions are below a specific action level.

Instead of measuring the actual organic emission rate, a TSDF owner or operator could estimate the emission rate for a TSDF unit by using theoretical or empirical emission models, or simulating the unit operation using an emission flux chamber. However, using an estimation method would not provide results for a specific TSDF unit as accurate as would be achieved by actual measurement of the organic emissions from the unit. Furthermore, to use an

estimation method for implementing standards for a specific TSDF tank, surface impoundment, or container unit would require extensive and detailed knowledge about the physical and chemical properties of the waste managed in the TSDF unit, the TSDF unit operating practices and, in some cases, the meteorology at the TSDF site. Also, this approach would require extensive time and resource commitments by EPA or the designated State authority enforcement personnel to check the estimation calculations for the purpose of verifying compliance with the regulations. Therefore, because of the complexity and burden on the permitting authority of using the estimation methods currently available and, as discussed above, the impracticality and expense of using actual measurements, EPA believes that specifying an action level based on an emission rate format for nationwide standards applicable to TSDF tanks, surface impoundments, and containers would not be a practical approach.

An alternative to using an emission rate format is to use a waste parameter as an indicator of the potential organic emissions from a particular hazardous waste. Because of the need to periodically confirm that a waste parameter remains below the action level, the potential emission indicator must be in a format that is relatively simple to determine by an owner or operator and can be expeditiously checked by enforcement personnel. Considering this need, EPA evaluated possible action level formats and decided that an action level format based on the volatile organics concentration in the waste is appropriate for all TSDF tanks, surface impoundments, or containers. In addition, the EPA decided that the vapor pressure of liquid wastes should also be used as an action level for some TSDF tank operations.

Volatile organics concentration in the waste is an indicator of the total quantity of organics in the waste likely to be converted from a liquid or solid state to a gaseous state and, consequently, be emitted to the atmosphere. Vapor pressure is an indicator of the quantity of volatile organic vapors that collect inside covered tanks. When wastes are stored in a covered tank, the concentrations of volatile organics in the vapors contained in the tank headspace (i.e., space between the liquid surface and the cover) stabilize at an equilibrium concentration that is directly related to the vapor pressure of the organics in the waste. These organic vapors can potentially be emitted to the atmosphere through the vents installed on the cover because of tank filling and emptying operations, as well as the expansion or contraction of the tank headspace resulting from daily changes in ambient temperature or barometric pressure.

The volatile organics concentrations of hazardous wastes managed in TSDF tanks, surface impoundments, and containers vary widely. For example, "off-spec" products (i.e., petroleum or chemical products that do not meet manufacturing specifications) can contain nearly 100 percent volatile organics. In contrast, aqueous wastewaters can contain less than 1 part per million by weight (ppmw) of volatile organics. The EPA investigated the sensitivity of total nationwide TSDF organic emissions to the volatile organics concentration action level value using the national impacts model and comparing the action level values ranging from 0 to 10 percent (0 to 100,000 ppmw). As the value is increased from zero, the total nationwide quantity of waste that would be managed in TSDF units required to use emission controls decreases rapidly. Preliminary evaluation of various action levels indicated that above a level of 3,000 ppmw significant organic emissions potential would not be regulated by the standards. Thus, more detailed analysis was conducted for a range of volatile organics concentration action levels from 0 to 3,000 ppmw.

The EPA has used vapor pressure action levels for previous rulemakings to control organic emissions from tanks. Under authority of the Clean Air Act, EPA promulgated new source performance standards (NSPS) for petroleum liquid storage tanks (40 CFR 60 subparts K and Ka) and volatile organic liquid (VOL) storage tanks (40 CFR 60 subpart Kb). Many hazardous wastes containing volatile organics are similar to the liquids regulated by these NSPS. To evaluate the appropriateness of using a vapor pressure action level for TSDF tanks, EPA evaluated control options with and without a vapor pressure action level applied to TSDF tanks.

3. Emission Controls Considered for Control Options

The level of organic emission reduction that would be achieved by a control option is based on the particular emission controls specified for waste management units into which is placed waste with volatile organic concentrations and vapor pressures greater than the specified action levels. As discussed in Section IV, EPA selected a volatile organic containment and control approach for reducing organic emissions from TSDF tanks, surface impoundments, and containers. Therefore, all of the control options evaluated by the impact analysis, at a minimum, require using covers for all TSDF tanks, surface impoundments, and containers that manage wastes with volatile organic concentrations greater than the specified action level.

The need to use a control device in combination with a cover installed on a TSDF tank, surface impoundment, or container is affected by the type of waste management activity performed in the unit. For example, surface impoundments that store wastes or treat wastes without mixing, agitating, or aerating can use a floating membrane cover which contacts the waste surface. This type of surface impoundment is referred to here as a "quiescent surface impoundment" to reflect the undisturbed state of the waste in the unit. Similarly, storing wastes or treating wastes without mixing, agitating, or aerating in a tank equipped with a fixed roof (i.e., a rigid cover) limits organic emissions. This type of tank is referred to as a "quiescent tank". Control options were developed to evaluate the impacts of allowing quiescent tanks and quiescent surface impoundments to use covers only.

In contrast, waste treatment activities which increase surface turbulence in the waste such as mixing, agitating, and aerating significantly increase organic emissions because of the enhanced mass transfer between the waste medium and the air. Also, treatment activities which require the waste to be heated or generate heat in the waste can increase organic emissions. Furthermore, the nature of some hazardous waste treatment processes such as aerating a waste using floating aeration equipment or mixing a waste with a fixative material during waste fixation prevents a cover from directly contacting the waste surface. Organic emissions from waste management units which cannot use contact covers (e.g., floating roofs, floating membrane covers) can be contained by erecting a structure around the unit (e.g., air supported structure, permanent building) or, for open-top tanks, installing a fixed roof to enclose the space above the waste surface. The organic vapors from the waste are confined inside the enclosure. However, if the enclosure is vented directly to the atmosphere, organic emissions will still occur. Therefore, to be an effective organic emission control, the enclosure vents must be connected to a control device or, for some tank applications

using fixed roofs, equipped with pressure-relief valves.

Organic vapors that are vented from covered or enclosed TSDF units can be controlled using either an organic removal control device or an organic destruction control device (refer to Section IV). A variety of control devices are available that when properly designed and operated can achieve high organic emission control efficiencies. Applicability of a specific type of control device to controlling organic emissions from TSDF waste management units depends on the size of the unit and the characteristics of the organic vapor stream vented from the unit. The EPA reviewed the performance and applicability of each organic emissions control device type discussed in section IV to develop emission control levels for the control options.

As the starting point for developing emission control levels for the control options, EPA considered using an organic emission control level that would be consistent with existing organic air emission standards. As discussed in section II, the subpart AA standards for TSDF process vents require control devices to be designed and operated to reduce organic emissions by 95 percent. Many State implementation plans and other decisions on control devices made under the Clean Air Act to provide protection from the human health and environmental effects of organic emissions (in particular, ambient ozone effects) require control of organic emissions by approximately 95 percent. A requirement for a 95 percent control level would allow the TSDF owner or operator the alternative of using either organic recovery or organic destruction control devices. Preliminary analysis indicated that applying a 95 percent control level nationwide to TSDF organic emission sources would significantly reduce cancer risks relative to the baseline level. However, a 95 percent control level would not reduce the added risk to the most exposed individual of contracting cancer (i.e., maximum individual risk) to the target risk range that historically has been used for other RCRA standards (discussed in section VI).

A higher nationwide organic emission control level could be achieved by using exclusively organic destruction control devices. Thermal vapor incinerators and the other types of combustion units discussed in Section IV are capable of achieving 98 percent organic emission control efficiencies. Repeating the preliminary cancer risk analysis assuming that a 98 percent control level nationwide is applied to TSDF organic emission sources reduced the cancer risk from the baseline level by less than 1 percent more than the reduction which would be achieved using a 95 percent control level. Furthermore, the maximum individual risk would still be greater than the target risk range which has historically been used for other RCRA standards.

Without a clear improvement in the level of cancer risk reduction that would be provided by a requirement for a 98 percent control level compared to a 95 percent control level, EPA decided that it would not be prudent public policy to require the exclusive use of organic destruction devices nationwide without regard to the content of individual organic toxic constituents in the gas streams vented to them. Instead, EPA believes that a better approach is to require a control level of 95 percent nationwide for organics as a class and to evaluate requiring control devices that reduce organic emissions beyond this level for vapor streams containing individual toxic constituents of concern as discussed in section VI. Organic destruction devices would then be applied selectively to the TSDF units that manage those wastes containing high levels of the individual toxic constituents which are creating the relatively high cancer risks to the exposed population. Thus, an organic emission control level of 95 percent was used for the control options evaluated to select the basis for the standards controlling TSDF organics as a class.

A requirement to reduce organic emissions by 95 percent provides the TSDF owner or operator with more control technology alternatives to consider in selecting the control device to use to comply with the standards. The owner or operator could use organic recovery control devices such as carbon adsorbers and condensers as well as organic destruction devices. Use of carbon adsorbers or condensers would allow recovery of the organics from gas streams with high organic contents for subsequent direct reuse at the TSDF site or sale as a solvent or fuel. Depending on the quantity of organics recovered and the value of the recovered organics, the cost of installing and operating an organic recovery device could be significantly less expensive (possibly offsetting the cost of control entirely) than an organic destruction device.

4. Control Options Selected for Impact Analysis

The control option action level and emission control screening investigations resulted in the evaluation of five control options to select the basis for the proposed standards. All five of the control options would require that all TSDF tanks, surface impoundments, and containers managing hazardous waste with a volatile organics content greater than a specified concentration would require the use of covers as a minimum level of control. The primary differences between the control options are the value used for the volatile organics concentration action level, and whether a closed vent system and control device is used in combination with the cover for the tank and surface impoundment units requiring emission controls.

Option 1 would require all TSDF tanks, surface impoundments, and containers storing or treating a hazardous waste with any amount of detectable volatile organics (i.e., a volatile organic concentration action level of 0 ppmw) to use control equipment. The control equipment requirements are: (a) each tank uses a cover with a closed vent system and control device except for each quiescent tank managing wastes with a vapor pressure less than 10.4 kPa which uses a cover without additional controls; (b) each surface impoundment uses a cover with a closed vent system and control device; and (c) each container uses a cover at all times except during waste loading/unloading operations, and submerged fill is used to load pumpable wastes.

Option 2 would require all tanks, surface impoundments, and containers storing or treating a hazardous waste with a volatile organic concentration greater than 500 ppmw to use control equipment. The control equipment requirements are the same as described for Option 1.

Option 3 would also require all tanks, surface impoundments, and containers storing or treating a hazardous waste with a volatile organic concentration greater than 500 ppmw to use control equipment. However, Option 3 differs from Option 2 in that a cover is used without additional controls on all quiescent tanks and quiescent surface impoundments. Specifically, the control equipment requirements are: (a) each tank uses a cover with a closed vent system and control device except for each quiescent tank which uses a cover without additional controls; (b) each surface impoundment uses a cover with a closed vent system and control device except for each quiescent surface impoundment which uses a cover without additional controls; and (c) each container uses a cover at all times except during waste loading/unloading

operations, and submerged fill is used to load pumpable wastes.

Option 4 would require all tanks, surface impoundments, and containers storing or treating a hazardous waste with a volatile organic concentration greater than 1,500 ppmw to use control equipment. The control equipment requirements are the same as described for Options 1 and 2.

Option 5 would require all tanks, surface impoundments, and containers storing or treating a hazardous waste with a volatile organic concentration greater than 3,000 ppmw to use control equipment. The control equipment requirements are the same as described for Options 1, 2, and 4.

B. Health and Environmental Effects of Control Options

1. Organic Emissions

Organic emissions react photochemically with other chemical compounds in the atmosphere to form ozone. Ozone is a major air problem in most large cities in the United States. The EPA estimates that more than 100 million people live in areas where the national ambient air quality standard for ambient ozone is not attained. Ozone is a pulmonary irritant that impairs normal human respiratory functions and aggravates pre-existing respiratory diseases. Exposure to ozone also increases the susceptibility to bacterial infections. In addition, ozone can reduce the yields of citrus, cotton, potatoes, soybeans, wheat, spinach, and other crops as well as damage conifer forests and causes a reduction in the fruit and seed diets of wildlife.

Reductions in organic emissions from TSDF units would have a positive impact on human health and the environment by reducing ambient ozone formation. Baseline nationwide organic emissions from TSDF are estimated to be approximately 1.8 million megagrams per year (Mg/yr). At this emission level, TSDF organic emissions account for approximately 12 percent of the total nationwide organic emissions from stationary emission sources. The estimated nationwide TSDF organic emissions assuming implementation of the individual control options are 93 thousand Mg/yr for Option 1, 96 thousand Mg/yr for Option 2, 130 thousand Mg/yr for Option 3, 140 thousand Mg/yr for Option 4, and 180 thousand Mg/yr for Option 5.

2. Cancer Risk and Incidence

To assess the risk of contracting cancer posed by exposure to organic emissions from TSDF, EPA estimated two measures of health risk. These are termed "annual cancer incidence" and "maximum individual risk" (MIR). Estimation of these health risk parameters requires EPA to make several critical assumptions regarding the TSDF plant configurations and operating practices, the composition of wastes managed at these TSDF, the cancer potency of the organics contained in these wastes, the emission of these organics to the atmosphere from TSDF sources, and the exposure of people living near TSDF to these air toxic emissions. The complex interrelationship of the various assumptions prevents EPA from definitively characterizing the estimated health risk parameter values as being over or underestimates.

The annual cancer incidence parameter represents an estimate of population risk and, as such, measures the aggregate risk to all people in the United States estimated to be living within the vicinity of TSDF. This risk value is based on the estimated number of excess cancers occurring in the nationwide population after a lifetime exposure (defined to be 70 years). For statistical convenience, the aggregate risk is divided by 70 and expressed as cancer incidences per year.

Annual cancer incidence was estimated for baseline and the five control options using EPA's Human Exposure Model (HEM), the composite cancer risk factor, and TSDF industry profile data bases introduced in Section III and described with more detail in Appendices D and E of the BID. Baseline nationwide annual cancer incidences from exposure to TSDF organic emissions is estimated to be 140 cases per year. The estimated nationwide TSDF cancer incidences assuming implementation of the individual control options are 6 cases per year for Option 1; 6 cases per year for Option 2; 8 cases per year for Option 3; 14 cases per year for Option 4; and 16 cases per year for Option 5.

The MIR parameter represents the maximum additional cancer risk (i.e., above background cancer risks) for any one person due to exposure for a lifetime to an emitted pollutant. The EPA estimates the MIR parameter by assuming exposure of the individual to the ambient air toxic concentrations occurs for 24 hours per day for a lifetime of 70 years. The EPA realizes that most people do not spend their entire lives at one location. However, it is completely possible for an individual to live in the same place for his or her entire life. Furthermore, other uncertainties in the analysis could lead to underestimating the risk. For example, the actual exposed subpopulations (e.g., children, young adults) may be more sensitive to the emitted air toxics than the reference adult male for which the unit risk factor extrapolations are based.

As applied to TSDF air emissions, the MIR parameter reflects the added probability that a person would contract cancer if exposed continuously over a 70-year period to the highest annual average ambient concentration of the air toxics emitted from a TSDF representing a reasonable worst-case situation. The use of a reasonable worst-case situation is consistent with the MIR analysis used in determining the standards to control organic emissions from process vents and equipment leaks at TSDF for the first phase of EPA's program to regulate air emissions under RCRA Section 3004(n) (55 FR 25486). The MIR was estimated for the baseline and each of the five control options using EPA's Industrial Source Complex Long Term Model (ISCLT) to calculate annual average ambient organic concentrations around an actual TSDF site that was chosen to represent a reasonable worst-case situation. The MIR value was obtained by multiplying the highest annual average ambient organic concentration modeled to occur at the facility boundary times the same composite cancer risk factor used to estimate annual cancer incidence. Detailed information about the ISCLT model and the detailed TSDF modeling is provided in the Appendix J of the BID.

When evaluating the MIR estimates for TSDF, it is important to remember that these values represent a reasonable worst-case situation. Thus, EPA expects few TSDF present risks as high as the risks estimated for the reasonable worst-case situation. Baseline MIR from exposure to TSDF organic emissions is estimated to be 2×10^{-2}. The estimated MIR assuming implementation of the individual control options are: 5×10^{-4} for Option 1; 5×10^{-4} for Option 2; 5×10^{-4} for Option 3; 8×10^{-4} for Option 4; and 9×10^{-4} for Option 5. These values are greater than the target risk levels for other promulgated RCRA standards which historically have been in the range of 1×10^{-4} to 1×10^{-6}. Section VI of this preamble describes EPA's plans to reduce further the risk from TSDF air emissions.

It is important to recognize for this analysis that the MIR estimates are also sensitive to several factors including type and configuration of units at the TSDF site, number of each type of unit, composition of waste managed in each unit, organic emission rate for each unit, location of TSDF site relative to where people live, and meteorology at the TSDF site. For example, one important

factor affecting the MIR value is the magnitude and rate of organic emissions from individual waste management units at the TSDF site. At the particular TSDF used as the basis for the MIR estimates, the major source of organic emissions contributing to the maximum ambient organic concentration associated with the MIR values is two large, uncovered surface impoundments used for aerated treatment, located adjacent to one another, approximately 25 meters (82 feet) inside the facility boundary (i.e., property line). If these units were located instead near the center of the TSDF site, then the ambient organic concentrations modeled at the TSDF property line would be lower, and the MIR values would show lower risk probabilities. Many existing TSDF do not have large organic emission sources located near the facility property lines and, consequently, actual ambient organic concentrations around these facilities would be expected to be significantly lower than the modeled concentrations.

Another important factor affecting the MIR value is the distance from the TSDF units to the location where the nearest person may live. For the MIR estimates, this distance was assumed to be a person living directly on the TSDF property line. In actuality, the vast majority of the exposed population lives further from TSDF property lines. If the assumption had been used for the control option impact analysis that the nearest resident lived at a less conservative distance beyond the TSDF property line, then the MIR values would show lower risk probabilities. For example, if the distance to the nearest residence is assumed to be an additional 25 meters (82 feet) beyond the property line, the MIR value for Options 1, 2, and 3 decreases from 5×10^{-4} to 1×10^{-4}.

The composition of organics in the emissions from individual waste management units at the TSDF site also affects the MIR estimates. For example, the TSDF site used as a basis for the MIR estimates did not report managing wastes containing dioxin. As discussed in Section III of this preamble, approximately one-half of the composite unit risk factor used for the MIR estimates is contributed by dioxin. Consequently, the MIR estimated for each of the control options is approximately two times higher than the value that would be estimated if dioxin is removed from the composite unit risk factor.

As discussed earlier in this section, the TSDF site chosen as the basis for the MIR estimates has a configuration and location which results in unusually high public exposure and health risk. This site clearly needs to be controlled. However, it could be argued that nationwide standards based on this source may result in emission controls for other TSDF sites which reduce risk at those sites well beyond the level which has traditionally been considered necessary for protection of human health. Therefore, EPA is reviewing alternative ways of ensuring that all TSDF sites do not pose significant risks to human health and the environment.

One option EPA is considering is whether to integrate its omnibus permitting authority into standard setting under RCRA section 3004(n). As discussed in section II of this preamble, omnibus permitting authority is used to address specific circumstances that are judged to warrant control beyond baseline standards. Using omnibus permitting authority, EPA could limit emissions from those TSDF sites with configurations or locations which pose unusually high risks and, thereby, establish baseline standards according to a source presenting a lower exposure scenario. This approach may lead to a lower cost standard and still protect human health and the environment. However, practical difficulties may make this approach unworkable. The EPA is concerned that the permitting process might be expensive and time consuming for both EPA and the industry. Sources suspected of posing unusually high risks would need to perform more extensive risk assessments which EPA must review. Furthermore, it is presently unclear what criteria EPA would use to decide which TSDF sites would be subject to the additional permitting requirements. If EPA were to decide to adopt this approach, questions remain regarding how to draw the dividing line between nationwide standards for TSDF developed under RCRA section 3004(n) and site-specific permit requirements implemented by the omnibus permitting authority of RCRA section 3005(c) (3); that is, the question would be which TSDF sites would be subject to omnibus permitting in addition to nationwide standards. The EPA requests comments on all of these issues.

During the course of reviewing the comments, EPA will also undertake a legal review to assess whether an approach relying in part on omnibus permitting would be within EPA's discretion in applying RCRA sections 3004(n) and 3005(c)(3), in light of the RCRA statutory language; its legislative history; past EPA practices under RCRA, see, e.g., 55 FR 25454, 25492/1 (June 21, 1990); the case law under RCRA, see, *e.g., NRDC* v. *U. S. EPA,* 907 F.2d 1146, 1163–65 (D. C. Circuit 1990); and the law relating to the standards promulgated under other environmental statutes, see, *e.g., E. I. DuPont de Nemours and Company* v. *Train,* 430 U. S. 112 (1977) (Federal Water Pollution Control Act). The EPA invites comments on this legal question as well.

The EPA based the MIR estimates on a TSDF site representing a reasonable worst-case situation so that EPA is more confident that decisions based on the analysis results consider not only the currently known situations but also situations occurring of which EPA is unaware or situations that may occur in the future.

3. Noncancer Effects

Noncancer health effects due to TSDF organic emissions can result from direct inhalation of airborne toxic chemicals emitted from the TSDF as well as indirect pathways such as ingestion of foods contaminated by air toxics or absorption of air toxics through the skin. An evaluation of noncancer health effects resulting from direct inhalation exposure to predicted ambient air concentrations of different air toxics in areas adjacent to TSDF was performed. However, methodologies for predicting effects from indirect exposure to air toxics for application to TSDF have not been developed at this time.

A screening evaluation was performed by EPA to assess the potential adverse noncancer health effects associated with acute and chronic inhalation exposure to 179 individual toxic constituents emitted from TSDF tanks, surface impoundments, and containers. This evaluation was based on a comparison of relevant available health data for the highest short-term average and long-term average ambient concentrations of each toxic constituent estimated for the same individual TSDF used for the cancer MIR estimates. Maximum short-term ambient concentrations (i.e., averaging times of 24 hours and less) were estimated using EPA's Industrial Source Complex Short-Term (ISCST) Model, and maximum long-term ambient concentrations (i.e., annual average) were estimated using the ISCLT model. Detailed information about these models and the detailed modeling of the ambient constituent concentrations for the individual TSDF are provided in Appendix J of the BID.

The screening evaluation results show that the modeled short-term and long-term ambient constituent concentrations were in most cases at least 3 orders of magnitude below inhalation health

effect levels of concern. These results suggest that adverse noncancer health effects are unlikely to be associated with acute or chronic inhalation exposure to TSDF organic emissions on a nationwide basis. However, because of the limited health data available for many toxic constituents, additional evaluation of noncancer health effects may be needed. The EPA is specifically requesting comments from the public on methodologies and use of health data for assessing the noncancer health effects of TSDF organic emissions.

The potential for indirect exposure to air toxics is a function of whether the airborne chemicals have deposited in the soil, migrated into underground aquifers, run off into surface waters, or bioaccumulated in the food chain following long-term surface deposition. Although not as yet modified for application to TSDF, methodologies used to predict indirect exposure thus far in other contexts have shown that the cancer risks resulting from the ingestion of foods and soil contaminated by some chemicals may be significant. Therefore, as part of its continuing effort to improve risk estimates from TSDF, EPA will evaluate the need to include an indirect pathway element in the TSDF risk analysis of cancer effects.

C. Implementation Impacts of Control Options

The EPA estimated the total nationwide costs to the TSDF industry to install and operate the emission control equipment specified by each of the five control options. Nationwide cost values were estimated for two basic cost categories, capital costs and annualized costs, using the national impact model described in Section III of this preamble. These nationwide cost estimates are based on the assumption that at every TSDF location, the owner or operator would install the specified emission control equipment on all of the tanks, surface impoundments, and containers used at the TSDF to store and treat the regulated waste with treatment to comply with the LDR occurring as the last step prior to disposal of the waste. In actuality, EPA expects that at many TSDF locations, the owner or operator (after becoming aware of the rule) would treat the waste to comply with the LDR at an earlier step in the waste management sequence reducing the volatile organic concentration of the waste below the action level, and thus avoid the costs of installing and operating control equipment on the downstream tanks, surface impoundments, and containers.

Capital cost represents the investment required by TSDF owners and operators to install the emission controls that would be required by a particular control option. The estimated nationwide capital costs to implement the individual control options are $2,100 million for Option 1, $1,700 million for Option 2, $960 million for Option 3, $690 million for Option 4, and $520 million for Option 5. Annualized cost represents the annual cost to TSDF owners and operators to repay the capital investment for the emission controls as well as to pay for operating and maintaining the emission controls. The estimated nationwide annualized costs to implement the individual control options are $930 million/yr for Option 1, $710 million/yr for Option 2, $360 million/yr for Option 3, $290 million/yr for Option 4, and $210 million/yr for Option 5.

Implementation of Options 1, 2, 4, or 5 would require periodic waste vapor pressure testing be performed if a TSDF owner or operator elects to not use a control device on a tank that manages a quiescent waste with a volatile organic concentration above the action level for the option. Option 3 does not have the organic vapor pressure restriction for quiescent wastes managed in tanks. The EPA's TSDF industry profile data base indicates that many existing TSDF tanks would qualify for this exception. Considering the cost to purchase, install, and operate a control device versus the cost to perform waste vapor pressure testing, owners or operators of these TSDF tanks would likely choose to perform periodic vapor pressure testing. Given the large number of tanks affected by the vapor pressure action level, the time and resources necessary for industry to determine compliance with the standards and for EPA or authorized State agencies to enforce the standards are expected to be lower for Option 3 than the other options.

D. Selection of the Basis of the Proposed Standards

The EPA selected one of the five control options as the basis for today's proposed standards using a decision framework based on EPA's historical approach of considering cost under RCRA only for those control options that provide equal protection of human health and the environment, except where the control options achieve historically acceptable levels of protection. Applying this decision framework, Option 3 was selected as the basis for today's proposed standards. The rationale for the selection of Option 3 is presented in this section.

To assess the degree of human health and environmental protection provided by each control option, EPA compared the organic emissions, cancer MIR, and annual cancer incidence values estimated for each of the five control options relative to the estimated baseline impacts. The level of confidence in the impact analysis was an important factor in EPA's assessment of the significance of the impact estimates with respect to human health and environmental protection. As was discussed in section III, limited availability of information required that, for the national impact analysis, EPA make certain critical assumptions about some hazardous waste characteristics and TSDF operating practices. The use of these assumptions adds a level of uncertainty to the impact estimates. The complexity of the estimation methodology and number of independent input parameters to the analysis prevents EPA from quantifying this uncertainty. However, while the estimated values may not reflect the actual differences in impacts between the various control options, EPA believes the estimated values do indicate the relative differences in human health and environmental protection provided by the five control options.

All of the control options achieve substantial reductions in nationwide organic emissions from TSDF. The estimated nationwide organic emissions reduction estimated for Options 1, 2, 3, and 4 is the same magnitude, approximately 1.7 million Mg/yr. Option 5 is estimated to provide lower nationwide organic emission reductions, approximately 1.6 million Mg/yr, than estimated for the other control options.

Both Options 1 and 2 are estimated to achieve the lowest cancer MIR (5×10^{-4}) and greatest reduction in annual cancer incidence (134 cases per year) of the five options. Option 3 also is estimated to achieve an MIR of 5×10^{-4} but the estimated annual cancer incidence reduction for Option 3 (132 cases per year) is slightly lower than the estimated reduction for Options 1 and 2. Options 4 and 5 are estimated to provide less reduction in both cancer MIR and annual cancer incidence than either Options 1, 2, or 3. The estimated MIR is higher for Option 4 (8×10^{-4}) and Option 5 (9×10^{-4}) compared to Options 1, 2, and 3 (5×10^{-4}). Annual cancer incidence reductions estimated for Option 4 (126 cases per year) and Option 5 (124 cases per year) are lower than the annual cancer incidence reductions estimated for Options 1, 2, and 3.

Options 1, 2, 3, and 4 are estimated to achieve the same level of nationwide organic emission reduction (1.7 million

Mg/yr). However, none of the five control options are estimated to reduce the individual lifetime cancer MIR to the target risk levels for other promulgated RCRA standards, which have been in the range of 1×10^{-4} to 1×10^{-6}. Moreover, none of the control options attain the target risk levels EPA generally has used to develop air emission standards for hazardous air pollutants under Section 112 of the Clean Air Act. Under Section 112 as in effect prior to November 15, 1990 (and Section 112(f) as amended), this level of MIR risk does not constitute a rigid line for making a determination of acceptable risk. The EPA recognizes that the consideration of MIR must take into account its strengths and weaknesses as a measure of risk. It does not necessarily reflect the true risk, but displays a conservative risk level which is an upper bound that is unlikely to be exceeded. While levels of individual risk greater than 1×10^{-4} become presumptively less acceptable, these risk levels would be weighed with other health risk measures and information in making an overall judgement on acceptability (54 FR 51656). On the basis of available information, EPA tentatively concluded that Options 1, 2, and 3 are more protective of human health than either Option 4 or 5. Furthermore, because of the uncertainty in the impact analysis, EPA cannot confidently discern whether the differences between annual cancer incidence reductions estimated for Options 1 and 2 versus Option 3 (134 versus 132 cases per year) could actually occur. Therefore, EPA concluded that Options 1, 2, and 3 are equally protective of human health and the environment.

When no control options achieve acceptable levels of protection, EPA's approach historically has considered cost under RCRA only for equally protective control options. Following this approach, EPA compared the implementation impacts for the equally protective Options 1, 2, and 3. The Option 3 control requirements differ from the Options 1 and 2 requirements by allowing more quiescent tanks and all quiescent surface impoundments to use covers without additional controls and without the need for vapor pressure test. Option 3 would be less expensive for the TSDF industry to implement than Options 1 and 2 because fewer TSDF tank and surface impoundment units would need to install and operate control devices in addition to covers. Option 3 would be easier to implement and enforce than Option 1 or 2 because this exception would not depend on the particular waste but rather the type of tank or surface impoundment being used.

In summary, including consideration of the estimated reductions in nationwide organic emissions and annual cancer incidence, EPA concluded that Options 1, 2, and 3 are equally protective of human health and the environment. Because Option 3 would be less expensive and easier to implement than either Option 1 or 2, EPA selected Option 3 as the basis for today's proposed standards.

E. Solicitation of Comments

Although Option 3 is selected as the basis of today's proposed standards, EPA believes that it is reasonable and prudent to continue consideration of other available alternatives to the proposed standards. Therefore, EPA is requesting comments from the public on the aspects of EPA's regulatory decisions made for today's proposed rulemaking discussed below as well as the methodology, assumptions, and data used for the current national impact analysis. In addition, EPA is planning to conduct its own study to gather more information regarding the TSDF industry. This study will include visits to selected TSDF for the purpose of obtaining firsthand information from TSDF operators regarding the waste management practices they are using to comply with other RCRA regulations (e.g., land disposal restrictions) and the practices they would anticipate using to meet the requirements of today's proposed standards.

Following a review of both the public comments on today's proposed standards submitted to EPA and the new TSDF industry data obtained by EPA, the methodology, assumptions, and data used for the national impact analysis will be reconsidered by EPA. If appropriate, EPA will modify the analysis and consider the new results in its evaluation of different control options. Consideration of comments combined with any new data provided by commenters as well as new data obtained by EPA could lead to selection of any one of the five control options described in today's proposal or possibly other control options. The EPA is especially interested in receiving comments on the following topics.

Comments are requested regarding the approach for controlling air toxic emissions from wastes containing chemicals that pose a significant human health or environmental threat but are managed by a small portion of the TSDF in the United States. Today's proposed standards would establish one set of nationwide standards applicable to all TSDF managing wastes containing organics. For example, although wastes containing dioxin are managed at a small portion of TSDF, EPA used a composite cancer unit risk factor for its national impact analysis in which dioxin contributes approximately one-half of the risk. An alternative approach may be to establish different standards under this rulemaking for TSDF based on different waste categories. For example, EPA could establish one set of standards for those TSDF which manage wastes containing dioxin and a different set of standards for those TSDF which do not manage wastes containing dioxin. The EPA solicits comment on whether natural divisions exist in the TSDF industry which would allow standards to be established for subcategories of TSDF. A third approach may be to remove dioxin from the computation of the composite risk factor in the national impacts analysis used as the basis for this rulemaking, and consider controls for dioxin emissions from TSDF in the third phase of EPA's program to develop hazardous waste TSDF air emission standards as described in section VI of this preamble.

The EPA requests comments on the reasonableness of its determinations concerning equal protection of human health and the environment. As discussed earlier in this preamble, because of uncertainty in the impact estimates EPA cannot confidently discern significant differences in the nationwide reductions of organic emissions and annual cancer incidence attributable to certain control options. For example, Option 2 has the potential to provide additional nationwide organic emissions and annual cancer incidence reductions beyond the levels estimated to be achieved by Option 3. These additional reductions could occur because Option 2 would require the use of covers with control devices on certain quiescent tanks and on quiescent surface impoundments. However, the accuracy of EPA's current national impact analysis prevents EPA from clearly identifying the extent of the additional reductions in nationwide organic emissions and annual cancer incidence, if any, that could actually occur if Option 2 were implemented. Thus, EPA solicits information to supplement the data bases used for the national impact analysis. Comments are also requested concerning whether there are additional human health and environmental benefits which should be considered in the selection of the basis for the standards.

Finally, EPA requests comments regarding its decision to propose

standards based on using the same action level throughout the entire waste management process (i.e., from the point where the waste is generated through disposal). An alternative approach would be to use different action levels for different stages in the waste management process. For example, EPA plans to analyze the effect of using an action level of 500 ppmw for waste management units up to the point where the waste is treated by waste fixation, and an action level of 1,500 ppmw for those waste management units in which waste fixation is conducted. Based on the results of the national impact analysis performed for today's proposal, this example approach could result in reductions in nationwide organic emissions and annual cancer incidence to levels that are between those estimated for Options 3 and 4 while decreasing the nationwide annualized cost for the standards by $240 million/yr.

VI. EPA Plans To Address Residual Risk

A. Need for Additional Risk Reduction

Today's proposed standards would result in substantial reductions in cancer risk compared to the baseline value. The MIR and annual cancer incidence are estimated to be reduced by greater than 90 percent. Although these reductions are significant, an MIR of 5×10^{-4} is estimated to occur after the application of the emission controls selected in Section V as the basis for the proposed standards. This remaining cancer risk, referred to here as "residual risk," is greater than the target cancer risk levels for other promulgated RCRA standards which historically have been in the range of 1×10^{-4} to 1×10^{-6}. The EPA is planning to investigate additional cancer risk reduction approaches beyond those considered in selecting the basis for today's standards as part of the third phase of EPA's program to develop hazardous waste TSDF air emission standards. These plans may be reconsidered if, based on its review of public comments received regarding today's proposal, EPA develops new cancer risk estimates for the second phase rulemaking and the estimated values are substantially lower.

The third phase will involve analyzing the cancer risk associated with exposure to individual toxic constituents remaining in the organic emissions from TSDF assuming the implementation of standards developed in the first two phases. If these analyses confirm the need for additional risk reduction, EPA may decide to provide additional human health and environmental protection by developing nationwide standards that will reduce the emissions of the specific toxic constituents of concern. During the interim while these analyses are being completed, EPA's omnibus permitting authority under 40 CFR 270.32(b)(2) will be used where EPA is aware of a site-specific need for additional controls.

Separate EPA projects are in progress to obtain more data about the management of hazardous waste at TSDF. The results from a nationwide survey of hazardous waste generators and TSDF are being compiled. These survey data contain more detailed information about TSDF hazardous waste characteristics and management operations than has been previously available to EPA. Because EPA is still in the process of reviewing, verifying, cataloguing, and analyzing the survey data, the full set of data could not be used for developing today's proposed standards. Limited use of selected subsets of the survey data was possible to improve EPA's understanding of waste fixation practices in tanks, surface impoundments, and containers, and to estimate the impacts of applying emission controls to 90-day tanks and containers. Once the survey is complete, improved data bases may allow risk estimates to be conducted to better assess the impacts from implementing today's proposed standards and to determine which facilities may have higher residual risk.

One of three possible outcomes could result from analyzing the risk associated with exposure to individual toxic constituent emissions from TSDF. First, revised risk estimates may show that the residual risk is lower than 5×10^{-4} and is within the historical range of other RCRA standards. Thus, no additional action may be required. Second, revised estimates may show that the residual risk is a problem at only a few specific facilities. Thus, additional risk reduction could be achieved under the RCRA omnibus permitting authority whereby site-specific risk reduction would be implemented on the basis of guidance developed by EPA for permit writers. Finally, the revised estimates may show that residual risk is a problem at many facilities. Thus, additional risk reductions would be pursued through the development of nationwide standards under RCRA section 3004(n).

The EPA is planning to assess residual risk for individual toxic constituents that meet two criteria: (1) The constituent is contained in wastes managed at existing TSDF: and (2) health effects data are available for the constituent (e.g., unit risk factors for carcinogens). Based on a preliminary evaluation of individual toxic constituents, EPA currently estimates that assuming implementation of today's proposed standards, approximately 15 to 30 individual toxic constituents may require additional controls.

B. Potential Residual Risk Reduction Approaches

The EPA has not yet selected an approach to reduce residual risk. Several potential approaches have been identified that could be used to achieve additional risk reduction by either implementing EPA's omnibus permitting authority on a site-by-site basis or promulgating a nationwide standard. Two potential approaches are described below in order to solicit comments about them and to provide owners and operators of TSDF that may install control technology to meet today's proposed standards with additional information to use in selecting methods of controlling organic emissions. If EPA decides to implement one of these strategies by nationwide standards then EPA will publish a proposed rule to that effect.

One approach would involve the application of additional emission controls beyond the level required by today's proposed standards for the management of hazardous wastes that contain specific toxic constituents. For each constituent of concern, a concentration would be specified for each constituent representing the level at which the constituent could be managed without exceeding a selected target risk at a model-sized facility representing a reasonable worst-case situation. The target risk has not been decided but will likely be between 1×10^{-4} and 1×10^{-6}. This concentration level would be the action level for the application of additional emission controls. Wastes with constituent concentrations above the specified action limits would be managed in units that are controlled to a greater degree than would be required by today's proposed standards. For example, additional levels of control could be achieved by applying a cover on a tank managing a quiescent waste with a volatile organic concentration below 500 ppmw or by adding a closed vent system and control device to a tank managing a quiescent waste with a volatile organic content above 500 ppmw.

Higher levels of control could be achieved by requiring a waste management unit using a closed vent system and control device to reduce organic emissions to a level greater than the 95 percent level required by the proposed standards. For example,

organic emission reductions of at least 98 percent could be achieved by using organic destruction control devices such as vapor incineration. As discussed in section V, EPA believes that a control device organic emission reduction efficiency of 95 percent is appropriate for nationwide standards that would reduce organic emissions as a class. However, organic destruction may be an appropriate emission control method when applied selectively to wastes with high concentrations of individual toxic constituents. For these situations, the reduction in toxic emissions and, consequently, risk may outweigh any additional secondary impacts from increased NO_x and CO emissions or increased energy consumption.

An alternative approach would be to limit the quantities of specific toxic constituents in the hazardous waste that could be managed at a particular TSDF. The total amount of each toxic constituent that could be managed at a TSDF over a period of time would be limited. For example, a TSDF would be allowed to manage hazardous wastes containing a particular constituent until the accumulated quantity of the constituent that was processed during a specified period (e.g., one month, one year) attained a specified mass limit. If the mass limit is attained, wastes containing the constituent could no longer be managed at the TSDF for the remainder of the period. The mass limit would be determined from calculations based on the maximum ambient concentration that could occur without exceeding a target risk. Managing constituent quantities above the mass limits would be expected to result in risks above the target risk, while managing constituent quantities equal to or below the mass limits would likely result in risks equivalent to, or below, the target risk.

This approach would probably specify two mass limits for each constituent. One mass limit would apply to the management of wastes in uncontrolled TSDF units such as open tanks. A second mass limit would apply to the management of wastes in controlled TSDF units such as tanks with covers vented to a control device. The mass limit applicable to a TSDF that manages wastes in uncontrolled units would be more stringent than the one for controlled units because the emission rate would be higher for uncontrolled units.

The two approaches described here are being considered as ways to reduce the residual risk remaining after implementation of the proposed standards. The additional emission control approach offers the advantage of easy implementation because a concentration action level, which is relatively easy to measure, is used as the means by which additional controls are triggered. However, because this only requires that emission controls be applied to wastes having toxic constituent concentrations above a certain action level, the approach would not control other factors that contribute to emissions (e.g., waste quantities managed). Consequently, applying controls to the wastes containing concentrations of constituents that exceed the action levels would not necessarily achieve a target risk level, which is a potential disadvantage of this approach. However, if the target risk is not achieved, EPA's omnibus permitting authority could be used to achieve further risk reduction. The mass-limit approach has the advantage that it would achieve the target risk. It also has a potential disadvantage in that it would be difficult to administer and enforce, and might reduce the nationwide waste management capacity below the levels that are needed to handle the wastes from all waste generators.

To take into account site-specific factors that affect the MIR, both approaches would provide a procedure for obtaining a variance from the control requirements. A variance procedure is needed for sites where the concentration of a particular constituent in the waste being managed at a TSDF could be higher than the selected action level while the actual health impact could be lower than the risk calculated by EPA due to factors unique to the specific site. An example would be managing a waste with constituent concentrations well above the action levels but in such a small quantity that the emissions, without additional controls, would not exceed the target risk. Under the variance procedure, the owner or operator would provide EPA with information demonstrating that emissions from the particular site would not exceed EPA's target risk. Upon review of the information (in essence, a site-specific risk assessment), EPA could exempt such a facility from the control requirements.

Just as it is possible to place waste with constituent concentrations above the action levels in a particular TSDF unit and not exceed the target risk, it is also possible to place waste with constituent concentrations below the specific constituent action levels in a particular TSDF unit and still exceed the target risk. The total quantity of the constituent in a waste may be large enough to result in a high cancer risk even though the wastes contain relatively low concentrations of constituents. To address this situation, EPA would prepare a guidance document to allow the permitting authority to assess site-specific risks. If the risk assessment indicated that emissions would result in exposures above the target risk, the permitting agency could require additional emissions control under its omnibus authority.

The EPA considered proposing additional requirements for individual constituents as part of today's proposed standards; however, the exact nature and extent of the constituent problem is unknown at the present time. While the total quantity of toxic constituents in the wastes placed in TSDF units nationwide is known to be large, current data are not sufficiently detailed to describe the distribution of those toxic constituents among the individual TSDF. In addition, the available site-specific data for individual TSDF do not provide adequate site descriptions needed for detailed facility risk modeling. Both types of data are necessary to accurately determine site-specific MIR. The national survey data now being compiled by EPA should significantly improve the hazardous waste characterization and TSDF industry profile data files used in the analyses and thereby provide a more accurate estimate of risk distribution. A preliminary analysis of those data indicate that simply applying additional technology-based controls on a nationwide basis will not necessarily reduce maximum risk to target levels. Therefore, a more detailed analysis of constituent emissions and control options that include nontechnology-based approaches is being conducted.

VII. Requirements of Proposed Standards

A. Applicability

Today's proposal would add air emission standards for TSDF tanks, surface impoundments, and containers to 40 CFR parts 264 and 265 in a new subpart (subpart CC). These proposed standards would be applicable to owners and operators of permitted and interim status TSDF under subtitle C of RCRA. The proposed 40 CFR 264 subpart CC standards would also be applicable to certain miscellaneous units by an amendment to 40 CFR 264.601 that would require the permit terms and provisions for a miscellaneous unit being permitted under 40 CFR 264 subpart X to include the relevant emission control

requirements specified by 40 CFR 264 subpart CC. The rationale for this amendment is discussed at the end of this section of the preamble.

In addition, amendments to 40 CFR 265 subparts I and J would add the relevant emission control requirements specified by the standards proposed today as 40 CFR 265 subpart CC to the requirements that a hazardous waste generator must comply with pursuant to 40 CFR 262.34(a) in order to exempt tanks and containers accumulating waste on-site for no more than 90 days from the RCRA subtitle C permitting requirements. The 40 CFR 265 subpart CC requirements would not apply to accumulation of up to 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 CFR 261.33(e) in containers at or near the point of generation pursuant to 40 CFR 262.34(c). Also, the proposed standards would not apply to generators of between 100 and 1,000 kilograms of hazardous waste in a calendar month who accumulate the waste in tanks and containers pursuant to § 262.34 (d) or (e). The rationale for including certain generator accumulation tanks and containers in today's proposal is presented in section VIII.

B. Exceptions

The proposed standards would require that organic emission controls be installed and operated on tanks, surface impoundments, and containers used to manage hazardous waste. An exception from the control requirements would be allowed for a unit provided that all waste placed in the unit after the effective date of the standards has a volatile organic concentration less than 500 ppmw. In other words, a waste determined to contain less than 500 ppmw volatile organics could be placed in a tank, surface impoundment, or container that is not controlled for organic emissions. The volatile organic concentration of the waste would be determined before the waste is exposed to the atmosphere or mixed with other waste at a point as near as possible to the site where the waste is generated. Therefore, under the proposed standards, if a waste stream is not determined to have a volatile organic concentration less than 500 ppmw, then the specified organic emission controls would need to be used on every tank, surface impoundment, and container into which that waste stream is subsequently placed at the affected facility. However, if during the course of treating a waste (using a means other than by dilution or evaporation into the atmosphere) the organic concentration of the waste decreases below 500 ppmw, emission controls would not be required on the subsequent downstream tanks, surface impoundments, and containers that manage this waste.

It is EPA's intention that this exception apply only to those units for which the owner or operator is reasonably certain that the volatile organic content of the waste will consistently remain below 500 ppmw. If an owner or operator cannot determine confidently that the volatile organic content of the waste placed in a unit will remain below 500 ppmw, then the owner or operator should install the required emission controls. Determination that the volatile organic concentration of the waste is less than 500 ppmw would be performed by direct measurement or by knowledge of the waste as described later in this section.

The EPA recognizes that there are treatment processes that can be used to remove or destroy organic constituents in a waste. Therefore, to encourage the efficient use of treatment processes for reducing TSDF organic emissions, the proposed standards have been drafted so that a TSDF owner or operator who treats a waste stream to reduce the volatile organic concentration below 500 ppmw by a means other than by dilution (or evaporation into the atmosphere) would not be required to apply emission controls (i.e., covers and, in certain cases, control devices) to the subsequent downstream tanks, surface impoundments, or containers managing that waste stream. Although the tanks, surface impoundments, and containers into which the treated wastes are subsequently placed would not need to use the proposed emission controls, the treatment process used to reduce the waste volatile organic content below 500 ppmw (and the conveyors to it) would still need to comply with the air emission control requirements specified in 40 CFR 264 or 265. The waste determination for treated wastes would require documentation that organics have actually been removed or destroyed and that the reduction in volatile organic concentration is not a result of dilution or evaporation into the atmosphere.

An exception from the control requirements would also be allowed if the owner or operator documents that at all times the waste placed in the unit complies with the treatment standards for organics specified by the land disposal restrictions (LDR) in 40 CFR 268, subpart D (discussed in section II). Because the LDR treatment standards are developed on the basis of using BDAT, treatment of wastes using BDAT is presumed to reduce the volatile organic concentration of a waste to below 500 ppmw. Thus, EPA concludes that documentation certifying that wastes meet these constituent concentration standards provides adequate assurance that the waste would have little or no organic emissions. The public is specifically requested to comment on the appropriateness of allowing this exception from the proposed standards.

C. Waste Determinations

1. Waste Volatile Organic Concentration Determination

a. Implementation. Waste determinations would not be required for waste placed in units that use the required organic emission controls. A waste determination would only be required when an owner or operator chooses to place the waste in a tank, surface impoundment, container, or miscellaneous unit that does not use the required emission controls because the waste consistently contains less than 500 ppmw volatile organics. In this case, the owner or operator would be required to periodically perform a waste determination to verify that only waste having a volatile organic concentration less than 500 ppmw is placed in units not controlled for organic emissions.

The types of waste for which an owner or operator may choose to perform a waste determination include a waste that is recurring or continuously generated with a volatile organic concentration consistently below 500 ppmw or a waste that results from a one-time occurrence (e.g., a product batch that does not meet customer specifications) that is believed to have a volatile organic concentration below 500 ppmw. At TSDF locations where the volatile organic content of the waste managed is highly variable and is not consistently below 500 ppmw (e.g., a commercial TSDF receiving wastes from many customers), EPA expects that the owners or operators would install and operate the emission controls required by the standards and avoid the need to perform waste determinations to segregate the wastes for management in controlled versus uncontrolled units.

b. Concentration Determination Methods. To determine whether a particular waste may be placed in a unit not controlled for organic emissions, the owner or operator would be required to conduct initial and periodic waste determinations. The proposed standards would allow the owner or operator to use one of two methods for determining that the volatile organic concentration of a waste is below 500 ppmw. The first

method would be by direct measurement of the waste volatile organic concentration. The second method would be by knowledge of the waste.

Direct measurement waste determination would require that at least four waste samples be collected and analyzed for volatile organic concentration. The samples would need to be collected as close together in time as is practical, so that any variation in results can be attributed to sampling and analytical variability rather than process variability. Sampling and analysis would be performed using a new test method, "Determination of Volatile Organic Concentration in Waste Samples," being proposed today for addition to "Standards of Performance for New Stationary Sources Reference Methods" (40 CFR part 60, appendix A) as Reference Method 25D and to "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication No. SW-846) as Test Method 5100. This method is described in Section IX. The results of the sample analysis would then be used to calculate a mean and standard deviation for the logarithms of the measured values of volatile organic concentration. The mean and standard deviation of the logarithms would then be used as input values for a statistical t-test. The statistical t-test involves adding the average of the logarithms of the measured volatile organic concentrations to an estimate of the measurement standard error (sampling and analytical error), and then comparing the appropriate value (exponential of the sum) to the 500 ppmw action level. If the waste volatile organic concentration result for the statistical t-test is equal to or greater than 500 ppmw, then the owner or operator would be required to place the waste in tanks, surface impoundments, and containers that comply with the control requirements proposed today. If the waste volatile organic concentration result for the statistical t-test is less than 500 ppmw, then the owner or operator would be allowed to place the waste in tanks, surface impoundments, and containers that are not controlled for organic emissions. A detailed description of this statistical calculation procedure is presented in appendix 1 to this preamble.

As an alternative to using direct measurement, an owner or operator would be allowed to use knowledge of the waste as a means of determining that the volatile organic concentration of the waste is less than 500 ppmw. Examples of information that could constitute acceptable knowledge include: (a) Documentation that no organics are involved in the process generating the waste; (b) documentation that the waste is generated by a process that is substantially similar to a process at the same or another facility which has previously been determined by direct measurement to have a volatile organic content less than 500 ppmw; or (c) previous speciation analysis results from which the total concentration of organics in the waste can be computed.

Under the proposed standards, owners and operators choosing to comply with the standards by determining that a waste has a volatile organic content less than 500 ppmw would be subject to the provision that the EPA could require at any time that the owner or operator verify compliance with the standards by performing a direct measurement waste determination (i.e., collecting a representative number of samples, analyzing the samples using Reference Method 25D or Test Method 5100, and applying the statistical calculation procedure). Thus, if EPA requires the owner or operator to perform this waste determination for a waste which has been placed in an affected tank, surface impoundment, container, or miscellaneous unit not using the required emission controls and the results of that determination indicate the waste volatile organic concentration is equal to or greater than 500 ppmw, then the owner or operator would be in noncompliance with the requirements of the proposed rule.

c. Concentration Determination Location. The location where the waste volatile organic content is determined can greatly affect the results of the determination. This occurs because the concentration level can decrease significantly after generation as the waste is transferred to, and managed, in various waste management units. Even when managed in a unit equipped with emission controls, a portion of the organics in the waste will be emitted since the controls are not 100 percent effective.

If the waste is directly or indirectly exposed to ambient air at any point in its management sequence, a portion of the organics in the waste will be emitted to the atmosphere, and the concentration of organics remaining in the waste will decrease. For high volatility organic compounds such as butadiene, all of the compound would evaporate within a few seconds of exposure to air. Similarly, emissions of organics from open waste transfer systems (e.g., sewers, channels, flumes) are expected to be very significant. To ensure that the determination of volatile organic concentration is an accurate representation of the emission potential of a waste upon generation, it is essential that the waste determination be performed at a point as near as possible to where the waste is generated, before any exposure to the atmosphere can occur.

For the reasons stated above, the waste determination must be based on the waste composition before the waste is exposed, either directly or indirectly, to the ambient air. Direct exposure of the waste to the ambient air means the waste surface interfaces with the ambient air. Indirect exposure of the waste to the ambient air means the waste surface interfaces with a gas stream that subsequently is emitted to the ambient air. If the waste determination is performed using direct measurement, the standards would require that waste samples be collected from an enclosed pipe or other closed system which is used to transfer the waste after generation to the first hazardous waste management unit. If the waste determination is performed using knowledge of the waste, the standards would require that the owner or operator have documentation attesting to the volatile organic concentration of the waste before any exposure to the ambient air.

When a waste generator is also the TSDF owner or operator (e.g., the TSDF is located at the waste generation site), performing a waste determination before the waste is exposed to the ambient air can be readily accomplished since the TSDF owner or operator has custody of the waste from the point of generation. However, for the situations where the waste generator is not the TSDF owner or operator (e.g., the waste is generated at one site and shipped to a commercial TSDF), the TSDF owner or operator would not have custody of the waste until it is delivered to the TSDF. In this case, the TSDF owner or operator may not have access to the waste before it is exposed to the ambient air. Consequently, it would be necessary for the hazardous waste generator to perform the waste determination if waste is to be placed in TSDF units not equipped with the specified emission controls.

The EPA considered whether the requirement to perform the volatile organic concentration waste determinations should be added to the standards applicable to generators of hazardous waste in 40 CFR part 262. A waste determination would only be required when a TSDF owner or

operator chooses to place the waste in unit that does not use the specified emission controls. Furthermore, EPA expects that owners and operators of commercial TSDF receiving waste from a variety of waste generators will likely install the required emission controls on all units in order to have the flexibility to handle varying quantities of waste regardless of the waste volatile concentration being above or below 500 ppmw. Therefore, adding a requirement to 40 CFR part 262 that waste generators perform the volatile organic concentration waste determination before shipping the waste to a TSDF may result in many waste generators having to incur the expense of performing unnecessary waste determinations. Instead, EPA decided that a better approach for situations where the waste is generated then shipped off-site to a TSDF for management in units not controlled for organic emissions would be to allow the TSDF owner or operator the option of either: (1) Accepting only waste which is accompanied by waste determination documentation certifying that the waste volatile organic concentration is below 500 ppmw: or (2) performing the waste determination once the waste is received at the inlet to the first waste management unit at TSDF provided the waste has been collected and then transferred to the TSDF in a closed system such as a tank truck, and the waste is not diluted or mixed with other waste containing less than 500 ppmw of volatile organics. The EPA is requesting comment on the need to add to part 262 a requirement that waste generators perform the volatile organic concentration waste determination.

The location where the waste determination would be made for any one facility will depend on several factors. One factor is whether the waste is generated and managed at the same site, or the waste is generated at one site and transferred to a commercial TSDF for management. Another important factor is the mechanism used to transfer the waste from the location where the waste is generated to the location of the first waste management unit (e.g., pipeline, sewer, tank truck). For example, if a waste is first accumulated in a tank using a direct, enclosed pipeline to transfer the waste from its generation process, then the waste determination could be made based on waste samples collected at the inlet to the tank. In contrast, if the waste is first accumulated in a tank using an open sewer system to transfer the waste from its generation process, then the waste determination would need to be made based on waste samples collected at the point where the waste enters the sewer before the waste is exposed to the ambient air.

If a waste determination indicates that the volatile organic concentration is equal to or greater than 500 ppmw, then the owner or operator would be required to place the waste in units complying with the control requirements being proposed today, and transferred from one unit to another in a closed system (i.e., pipe or other transfer mechanism that is neither open nor vented to the atmosphere) until the waste is treated to remove or destroy organics so that the volatile organic content is below 500 ppmw.

d. Concentration Determination Frequency. Variations or changes in the process producing a waste may cause the volatile organic concentration of the waste to change. Therefore, EPA is proposing to require repetition of the waste determination by either direct measurement or knowledge as a condition for continued placement of the waste in units not controlled for organic emissions. The EPA considered three alternatives for the concentration determination frequency. All of the alternatives would require a waste determination be performed when there is a change in the waste being managed or a change in the operation that generates or treats the waste such that the regulatory status of the waste may be affected. The alternatives differ in the frequency of repetition in the absence of any waste or process changes, and would require either: (1) No periodic repeat determinations; (2) periodic repeat waste determinations at a specified frequency; or (3) periodic repeat waste determinations at a frequency established on a site-by-site basis by negotiation between the owner or operator and the permit writer.

Under the first alternative, once the initial determination was made that the volatile organic concentration of a waste is below 500 ppmw, no additional waste determinations would be made unless there is a change in the waste being managed or a change in the operation that generates the waste that may affect the regulatory status of the waste. From EPA's perspective of regulatory enforcement, this alternative is not a reasonable choice because it increases the likelihood of inconsistent implementation of the proposed standards by owners and operators. The alternative would not provide EPA with information to evaluate how effective each owner or operator is in checking the volatile organic content of the waste being placed in waste management units not using the specified organic emission controls and, thus, ensuring that the waste volatile organic concentration has not increased above 500 ppmw because of unintentional changes in the waste generating process or in the raw materials. The EPA believes these variations could be substantial and would be of special significance for wastes that have a measured volatile organic concentration near 500 ppmw because of the likelihood that there could be excursions above the action level. Any such excursions would be inconsistent with EPA's objective of allowing waste to be placed in units not controlled for organic emissions only if the volatile organic concentration of the waste does not exceed the 500 ppmw limit. Because of the increased possibility of not meeting the proposed emission control requirements, this alternative could be less protective of human health and the environment than the other alternatives considered.

Under the second alternative, waste determinations would be made when known changes occur in the waste or waste generating activity and, in addition, waste determinations would be made at a fixed, uniform frequency for all facilities. The periodic waste determinations would be more likely to detect unintentional or unperceived changes in the waste volatile organic concentration provided the determination frequency was set sufficiently high. Thus, periodic waste determinations would overcome the disadvantage of the first alternative associated with unintentional or unperceived changes in waste volatile organic concentration.

Under the third alternative, waste determinations would be made on a periodic basis at a frequency determined by negotiation between the permit writer and the owner or operator. While this alternative has the advantage of establishing the waste determination frequency based on unique characteristics of the waste or waste generating activity, it has the disadvantage of requiring negotiations between the owner or operator and the permitting authority (i.e., EPA or authorized State agency). This approach is currently used by EPA for several other RCRA regulations; however, because most TSDF will initially be subject to the interim status rules in 40 CFR part 265, which do not require prior review and approval before operation, EPA is hesitant to include provisions that would require negotiations with the permitting authority. Also, in some cases, the waste determinations would be performed by generators, and

because generators are not required to obtain RCRA permits there would be no permit negotiations.

Considering the advantages and disadvantages of the different alternatives, EPA concluded that requiring waste determinations on a fixed, uniform frequency is the most appropriate approach. Regular, periodic waste determinations are desirable because of the potential variability in waste makeup and because, once a waste is mismanaged and organics are released to the air, the damage to the environment may be done; i.e., the released organics cannot be removed from the ambient air except slowly by long-term, natural events.

Given the decision to use a specific, periodic waste determination frequency, the question remains as to what frequency should be required. Frequent waste determinations would shorten the period of time during which waste organic concentrations unknowingly changed and were not detected. However, frequent waste determinations may be unnecessary for some wastes. For wastes that have highly variable volatile organic concentrations, the interval between determinations would need to be shorter than for wastes with less variable volatile organic concentrations if the results are to be informative. The EPA considered two alternatives for periodic waste determination frequencies for situations when there is no change in the waste being managed or the operation that generates the waste: (1) A monthly frequency with a statistical procedure for using less frequent intervals; and (2) an annual frequency.

The first alternative would require waste determinations to be performed on a monthly basis with a procedure for establishing a less frequent interval based on the variability of the waste determination results for the initial 6-month period. After 6 months (the initial determination plus five subsequent, consecutive monthly determinations), a statistical calculation procedure would be used to determine if the waste determination frequency could be less frequent (e.g., semiannual or annual). This procedure would be separate from the statistical calculation procedure described earlier for the direct measurement waste determination. A standard statistical t-test would be used to determine the variability of the volatile organic concentrations measured for the samples collected during the preceding 6 months. The average of the logarithms of the measured volatile organic concentrations would be added to an estimate of the sampling and analytical error and, then, the resulting value would be compared to the 500 ppmw limit. If the value were less than 500 ppmw, the owner or operator would be allowed to extend the waste frequency interval to a longer period. If the value were equal to or greater than 500 ppmw, then the owner or operator would be required to continue performing the waste determinations on a monthly interval. A more detailed description of this statistical calculation procedure is provided in appendix 1 to this preamble.

The second alternative would require for situations when there is no change in the waste being managed or the operation generating the waste, that a waste determination be performed once per year. This alternative would apply the same waste determination interval to all facilities and would not require use of the statistical calculation procedure needed for the first alternative to establish a site-specific interval. Consequently, an annual waste determination interval would be simpler to implement by the TSDF owner or operator. Also, the annual interval would be easier to enforce by EPA or authorized State agencies because enforcement personnel would not need to conduct a site-specific calculation check before being able to verify that the waste determinations at a particular facility are being performed in compliance with the required waste determination interval. The EPA concluded that an annual waste determination interval would provide a reasonable balance between minimizing organic emissions and the ease of implementing and enforcing the standards. Therefore, today's proposal would require that an owner or operator be required to repeat the waste determination at least annually and, additionally, every time there is a change in the waste being managed or in the operation that generates or treats the waste that may affect the regulatory status of the waste. However, EPA is requesting comment on the appropriateness of both the requirement for periodic waste determinations and the selection of an annual waste determination frequency.

e. Waste Sampling Requirements. Owners or operators that choose to use direct measurement must consider the variability of the waste when collecting representative samples to be analyzed. Waste variability can be categorized as spatial or temporal. Both types of variability can interact and influence waste analysis results.

Spatial variability refers to vertical or horizontal concentration gradients that are often exhibited by a waste contained in a tank, surface impoundment, or container. To minimize spatial variation, the proposed Reference Test Method 25D would require that waste samples be collected whenever possible from an enclosed pipe discharging the waste from the waste management unit, and that a static mixer be used in the pipe to reduce stratification.

Temporal variability refers to changes in the volatile organic concentration of the waste generated by a process over time because of process variations, changes in raw materials, or other factors. To ensure that the waste determination is based on the expected maximum volatile organics concentration, EPA is proposing that four or more waste samples be collected at a point in time when the volatile organic concentration in the waste is as high as reasonably expected for the particular process. In setting the minimum number of samples at four, EPA is seeking a balance between obtaining sufficient data to statistically characterize the volatile organic concentration of a waste and the burden imposed on the owner or operator to collect the samples. Four measurements were judged by EPA to be the minimum required to estimate the measurement variability of volatile organic concentration samples from a waste.

f. Alternative Procedures for Treated Waste. The proposed standards would allow a special provision for a situation when the waste exiting a treatment unit has volatile organic concentrations less than 500 ppmw, and the quantity of waste leaving the treatment unit is less than or equal to the total quantity of waste entering the unit. For this situation, the treated waste would be allowed to be placed in subsequent waste management units that are not controlled for organic emissions. When one or more of the wastes entering the treatment unit has a volatile organic concentration less than 500 ppmw, an owner or operator would need to document that organics have been removed from the waste and that the reduced concentration is not the result of dilution due to mixing of wastes having volatile organic concentrations above 500 ppmw with wastes having volatile organic concentrations below 500 ppmw.

One method for determining that organics have been removed from the treated waste involves calculating a weighted average volatile organic concentration for the waste entering the treatment unit. The average volatile organic concentration of the waste

exiting the treatment unit must be less than the computed weighted average concentration in the waste entering the treatment unit to confirm that no dilution of the waste has occurred. The equation that is used to calculate this level is as follows:

$$C = \frac{\sum_{j=1}^{m}(Q_{a_j} \times 500\ \text{ppmw}) + \sum_{i=1}^{n}(Q_{b_i} \times C_{b_i})}{\sum_{j=1}^{m} Q_{a_j} + \sum_{i=1}^{n} Q_{b_i}}$$

Where:

C = volatile organic concentration action level for the waste after treatment (ppm by weight)

Q_{aj} = quantity of each waste stream (j) to be treated that has a volatile organic concentration at the tity of each waste stream (i) to be treated that has a volatile organic concentration less than 500 ppmw (Mg)

C_{bi} = volatile organic concentration of waste stream Q_{bi}

m = the number of waste streams greater than or equal to 500 ppmw

n = the number of waste streams less than 500 ppmw.

The effect of using this equation to calculate a weighted average concentration is to ensure that the waste streams with a volatile organics content in excess of 500 ppmw entering the treatment unit actually have been removed, and not just diluted.

In lieu of calculating the weighted average concentration in situations where a treatment unit has multiple input wastes with some having volatile organic concentrations above and some below the 500 ppmw action level, an owner or operator may choose to document that the volatile organic concentration of the output waste is no greater than the concentration in the input waste that has the lowest concentration. This procedure ensures that no dilution of the waste to lower the volatile organic concentration has occurred. The proposed standards would allow the volatile organic concentration of waste to be determined using either direct measurement or knowledge of the waste or treatment process.

These alternatives for determining that a treated waste has a volatile organic concentration below the 500 ppmw action level and that no dilution has occurred were identified by EPA as reasonable means for determining that the treated wastes do not need to be placed in units using the emission control requirements of today's proposal. However, because there are other approaches to making this determination, EPA requests the public to comment on the appropriateness of the method presented.

2. Waste Organic Vapor Pressure Determination

For wastes having a volatile organic concentration of 500 ppmw or more that are placed in tanks, today's proposal would require that the tanks be equipped with certain organic emission controls depending on the tank capacity and the waste organic vapor pressure as described later in this section. Therefore, compliance with the standards for some tanks would depend on the ability of the owner or operator to measure the organic vapor pressure of the waste placed in the tank and determine that the vapor pressure is below the applicable limit. Measurements of vapor pressure could be made using the proposed Reference Method 25E or Test Method 5110 or other acceptable methods as described in section IX. To make a vapor pressure determination, a waste sample would be required to be collected prior to the point where the waste enters the tank. Because the organic vapor pressure varies as a function of temperature, measurements would be required to be taken at the maximum temperature that is reasonably expected to occur.

D. Control Requirements

The basis for the control requirements being proposed today are the control technologies specified for Option 3 as discussed in section V. These control technologies are described in detail in chapter 4 of the BID which discusses the basis for the estimates of emission reductions that each type of control would be expected to achieve. These controls have been successfully applied to emission sources that are the same as, or similar to, those that occur at hazardous waste TSDF, and are judged to be appropriate controls for the sources regulated by today's proposed standards.

In preparing specific provisions of today's proposal, existing EPA regulations that address the same or similar emission sources were consulted for guidance in developing the detailed regulatory language and in some cases were adopted directly for use in the standards proposed today. For example, requirements for certain tank control equipment were taken directly from existing relevant Clean Air Act rules for storage of volatile liquids in 40 CFR 60 subpart Kb, and the inspection frequencies for containers and surface impoundments were taken directly from existing RCRA regulations in 40 CFR part 264 subparts I and K, respectively.

1. Tanks

Today's proposed standards would require that organic emission controls be used on a tank into which is placed hazardous waste containing 500 ppmw or more of volatile organics. Because several equivalent emission controls for tanks are available (as discussed in Section IV), an owner or operator would have the flexibility to use any one of several emission controls in order to comply with the standards. In addition, only a fixed roof cover would be required on those tanks that meet all of the following conditions: (1) The waste placed in the tank remains in a quiescent state (i.e., not mixed, agitated, or aerated), (2) the tank capacity and waste organic vapor pressure are not within the categories regulated by 40 CFR 60 subpart Kb, (3) no waste fixation occurs in the tank, and (4) no heat is added to or generated by processes occurring in the tank.

To ensure that organic emissions are effectively controlled, the proposed standards would require the fixed roof cover to completely enclose the tank so as to form a closed system which is vented only through the control device during normal operating conditions. The closed vent system and control device would be required to meet the design specifications described later in this section under the heading "Closed Vent Systems and Control Devices". For tanks required to use only a fixed roof cover, the vents in the cover would need to be equipped with a pressure-relief valve, a pilot-operated relief valve, a pressure-vacuum (PV) valve, or an equivalent pressure-relief device. These devices would be required to remain closed except when tank venting is required to prevent physical damage or permanent deformation of the tank or cover. For all tanks using fixed roof covers, the cover and all openings in the cover would be required to be designed and operated with no detectable emissions as determined by the procedures specified in Reference Method 21 in 40 CFR 60 Appendix A. All openings in tank covers such as hatches would be required to be sealed (e.g., gasketed, latched) and kept closed at all times when wastes are in the tank except during inspection and maintenance.

Pressurized tanks are designed to operate at internal pressures above atmospheric and thus operate as closed systems that do not emit organic emissions during normal storage conditions. An owner or operator would

be allowed to comply with the proposed regulation by the use of a pressurized tank. This tank would be required to be designed to operate in excess of 204.9 kPa. This pressure has been determined to be adequate to prevent release of emissions when wastes with the highest reasonably expected vapor pressures are stored at the highest reasonably expected temperatures. Pressurized tanks would be required to operate with no detectable emissions as determined by the procedures specified in Reference Method 21.

Under the authority of the Clean Air Act, EPA has promulgated new source performance standards (NSPS) for storage tanks constructed or modified after July 23, 1984 that contain volatile organic liquids (40 CFR 60 subpart Kb). These standards require that tanks with a capacity equal to or greater than 75 m^3 (approximately 20,000 gallons) but less than 151 m^3 (approximately 40,000 gallons) containing organic liquids with a vapor pressure greater than 27.6 kPa (approximately 4.0 pounds per square inch) and tanks with a capacity equal to or greater than 151 m^3 containing organic liquids with a vapor pressure greater than 5.2 kPa (approximately 0.75 pounds per square inch) be equipped with one of the following air pollution controls: (1) A fixed roof and an internal floating roof, (2) an external floating roof, (3) a closed vent system and control device, or (4) emission controls that are equivalent to one of the first three. All tanks with a capacity greater than 75 m^3 containing organic liquids with a vapor pressure greater than 76.6 kPa are required to use a closed vent system and control device to control organic emissions.

The EPA views the controls required by the NSPS for volatile organic liquids as the minimum control for any large tank containing organic hazardous waste, regardless of the date of construction of the tank. Accordingly, the tank control requirements specified in 40 CFR part 60 subpart Kb are incorporated as minimum control requirements for tanks in the standards proposed today for hazardous waste TSDF. An exception to this is the subpart Kb requirement that requires each tank with a capacity greater than 75 m^3 and containing an organic liquid with a vapor pressure greater than 76.6 kPa to use only a closed vent system and a control device. This requirement is not included in the standards proposed today because EPA does not expect wastes managed at TSDF to have vapor pressures near or above 76.6 kPa. The EPA requests comments on this decision.

The EPA believes that most existing tanks at TSDF are smaller than the sizes regulated by subpart Kb. Consequently, including the subpart Kb requirements in today's proposal should have little or no additional impacts. However, making the subpart Kb control requirements the minimum requirements for today's proposed standards would ensure that any existing large tanks used for the management of hazardous waste at TSDF are controlled at least as effectively as new, modified, or reconstructed tanks storing volatile organic liquids.

2. Surface Impoundments

Today's proposed standards would require that a cover and closed vent system that routes the gas stream to a control device that reduces organic emissions by at least 95 percent be used on a surface impoundment into which is placed a hazardous waste containing 500 ppmw or more of volatile organics. In addition, a floating synthetic membrane cover that contacts the waste surface can be used alone provided all of the following conditions are met: (1) The waste placed in the surface impoundment remains in a quiescent state (i.e., not mixed, agitated, or aerated), (2) no waste fixation occurs in the surface impoundment, and (3) no heat is added to or generated by processes occurring in the surface impoundment.

To comply with the proposed standards for surface impoundments, a nonquiescent surface impoundment would need to be equipped with an air supported structure or rigid structure that vents the gas stream from the enclosure to a control device. Contact covers (i.e., floating membrane covers) would only be allowable for quiescent surface impoundments because application of such a cover to a nonquiescent surface impoundment may not be physically possible, and would, at best, be impractical. Also, as discussed in Section IV, use of an air-supported structure without a control device would not provide effective organic emission control. Consequently, the standards would require that where an air-supported structure is used, a control device for both quiescent and nonquiescent surface impoundments be used also.

The use of floating membrane covers would be allowed only for quiescent units that are not used for waste fixation or other heat generating treatment processes (e.g., some neutralization processes are exothermic). The restrictions on the use of this control technique were included because of the potential for increased emissions from waste management units when the temperature is elevated. Under conditions of elevated temperature, volatilization of organics increases, thereby resulting in higher organic emissions. Consequently, all units used for heat generating treatment processes would be required to use covers in conjunction with control devices.

To ensure that organic emissions are effectively controlled, the proposed standards would require the surface impoundment cover (i.e, floating membrane cover, air-supported structure, or any other types selected by the owner or operator) and all openings on the cover to be designed and operated with no detectable emissions as determined by the procedure in Reference Method 21. All openings in the surface impoundment covers such as hatches and access doors would need to be sealed (e.g., gasketed, latched) and kept closed at all times when wastes are in the surface impoundment except during inspection and maintenance. Vents in the surface impoundment would be required to be operated with no detectable emissions except when venting is required to prevent physical damage or permanent deformation of the cover or surface impoundment. The closed vent system and control device would be required to meet the design specifications described later in this section under the heading "Closed Vent Systems and Control Devices".

For quiescent surface impoundments that use floating membrane covers, the covers would be required to cover the entire surface area of the impoundment when the impoundment is filled to capacity, and to be designed and installed to minimize volatile organic emissions. The standards would require that the cover be fabricated using high-density polyethylene (HDPE) having a thickness of at least 2.5 millimeters (100 mils) as the membrane material, or a material with equivalent permeability properties and other appropriate physical and chemical properties. Selection of the cover material was made on the basis of existing applications of HDPE covers on landfills and surface impoundments which have demonstrated that the material is compatible with hazardous waste and that airtight HDPE covers can be designed and installed on surface impoundments. The 2.5 millimeters thickness was selected because it is the thickest HDPE commercially available and was included as a requirement based on theoretical mass transport calculations presented in Appendix H of the BID which indicate that increasing membrane thickness significantly

lowers the volatile organic permeation rate. The proposed standards would require that surface impoundment covers be in place at all times that any waste is contained in the impoundment except during inspection, maintenance, or removal of residues through one of the cover openings, or during closure of the impoundment.

Although there is no theoretical size limit on floating synthetic membranes, as discussed in Chapter 4 of the BID, at very large sizes they become difficult to handle because of their weight. One consequence of this difficulty is that owners and operators of large impoundments may choose to convert from the use of impoundments to the use of tanks rather than installing covers.

3. Containers

Containers are defined in 40 CFR 260.10 as any portable device in which a material is stored, transported, treated, disposed of, or otherwise handled. Containers include (but are not limited to) drums, barrels, dumpsters, tank trucks, rail cars, dump trucks, ships, and barges. Owners and operators who store, handle, or prepare hazardous waste for management in containers are required under 40 CFR 264.173 and 40 CFR 265.173 to keep hazardous waste containers closed during waste storage except when waste is added or removed and are required not to open, handle, or store hazardous waste containers in a manner which may rupture the container or cause it to leak. Today's proposal would not change these requirements but would clarify that the intent of the existing rules is to have container covers form a tight seal. In addition, today's proposal would require that the cover be in place at all times during preparation, handling, and storage of hazardous waste except when waste is being added or removed. Today's proposal is also adding provisions that would require the following; (1) that container storage be carried out with no detectable emissions; (2) that submerged fill methods be used for placing pumpable waste in containers; and (3) that enclosures equipped with a closed vent system and control device be used to control emissions from waste fixation and heat generating processes that are carried out in containers.

The EPA determined that significant emissions may be released to the atmosphere when pumpable waste (i.e., liquid, slurry, or sludge waste that can be conveyed using a pump and associated piping) is being loaded into containers. It was further determined that if container loading is conducted by introducing waste into a container above the waste surface, i.e., by splash loading, emissions from the process are substantially increased. Consequently, today's proposal would control emissions from container loading or filling operations by requiring the use of submerged fill techniques for all pumpable wastes. In submerged fill, waste is introduced into a container through a pipe that extends beneath the surface of the waste in the container. This filling method minimizes emissions caused by agitation and splashing during filling.

Piping used for submerged filling of containers would be required to extend to within a distance no greater than two diameters of the fill pipe of the bottom of the container while the container is being filled. This provision would ensure that if a waste contains solids, the solid particles would be able to clear the end of the fill pipe rather than accumulate at the end of the pipe and possibly restrict the flow of material. Requiring the end of the pipe to extend to a point near the bottom of the container is necessary to ensure that the end of the pipe is beneath the surface of the waste during most of the filling process. When a container is being filled, only the area required for the loading inlet and appropriate vent area would be allowed to be open to the atmosphere.

4. Closed Vent Systems and Control Devices

For units required to use closed vent systems and control devices, EPA is proposing that the control device be operated whenever any waste is in the unit. The closed vent system would be required to be operated with no detectable emissions. The vent system consists of the piping, connections, and (if used) the flow inducing device that transport organic vapors from the unit to the control device. To achieve the maximum organic emission reduction, the vent system must be closed and not allow any organic vapors to escape directly to the atmosphere prior to the vapor stream entering the control device. Therefore, it is necessary to design and operate the vent system to ensure no detectable organic emissions from the vent system components.

The proposed standards would require that control devices be designed and operated to either achieve a total organic compound emission reduction efficiency of at least 95 percent, or meet specific performance requirements promulgated under 40 CFR 264 Subpart AA (specifically § 264.1033(c)–(d)) for control devices used to reduce organic emissions from TSDF process vents. Therefore, control devices that may be used to comply with today's proposed standards include organic destruction control devices such as thermal vapor incinerators, catalytic vapor incinerators, boilers, process heaters, and flares as well as organic recovery control devices such as carbon adsorbers and condensers. Applicability of the various control device types to a particular emission source will depend on the characteristics of the organic vapor stream that would be vented to the control device. As discussed in Section IV and Chapter 4 of the BID, these control devices when properly designed and operated have been demonstrated to achieve a total organic compound emission reduction efficiency of at least 95 percent as would be required by today's proposal.

If an enclosed combustion device (i.e., thermal vapor incinerator, boiler, or process heater) is used, it would need to be designed and operated to achieve either a total organic compound emission reduction efficiency of at least 95 percent or achieve a total organic concentration of 20 ppm by volume (ppmv) corrected to 3 percent oxygen on a dry basis. In lieu of an owner or operator having to develop a site-specific design to achieve the 95 percent or 20 ppmv level, the proposed standards would allow an enclosed combustion device to be used to comply with the standards that operates at a minimum residence time of 0.5 seconds and a minimum temperature of 760 °C. These are general design criteria that have been established for other EPA rulemakings under the Clean Air Act as the minimum conditions necessary to achieve the required 95 percent control efficiency. The lower limit of 20 ppmv would be provided for enclosed combustion devices to allow for the decline in achievable destruction efficiency that occurs with decreasing inlet organic concentration below approximately 2,000 ppmv. This limit is based on an analysis performed for EPA rulemakings under the Clean Air Act for the synthetic organic chemical manufacturing industry (48 FR 57547).

If a flare (an open combustion device) is used, the proposed standards require specific design and operating criteria to be met for steam-assisted, air-assisted, and nonassisted flares. A vapor stream being combusted in a steam-assisted or air-assisted flare would need a net heating value of 11.2 megajoules per standard cubic meter (MJ/scm) (300 Btu/scf). A vapor stream being combusted in a nonassisted flare would need a net heating value of 7.45 MJ/scm (200 Btu/scf). These restrictions on the use of flares to vapor streams with a net heating value above certain limits were included to ensure that flares will

achieve an emission reduction of at least 95 percent. All flares would need to be designed and operated with no visible emissions as determined by the procedures of EPA Reference Method 22 except for no more than a total of 5 minutes during any 2-hour period. The flare would need to be in operation at all times that emissions could be vented to it, and a pilot flame would need to be present whenever the flare is in operation. The calculation procedures for determining the net heating value of the gas being combusted and other design specifications (e.g., exit velocity) are included in the standards.

While the general design criteria necessary to achieve at least 95 percent organic control efficiency can reliably be established for enclosed combustion devices and flares, general design criteria for carbon adsorbers, condenser, or other organic recovery control devices cannot be specified on an industry-wide basis. Therefore if a carbon adsorber, condenser, or other type of organic recovery control device is used, the owner or operator would need to develop a site-specific design for the control device to achieve an organic control efficiency of at least 95 percent.

Owners or operators who use control devices to comply with today's proposed regulation would be required to document that each control device is designed to achieve the requirements specified by the standards for the particular type of control device. This documentation would consist of control device design plans (e.g., specifications, diagrams). The EPA believes that the engineering design practices for control devices are sufficiently established that the design documentation alone provides the necessary evidence that the desired level of performance is achieved and, when supplemented by control device monitoring data, adequately ensures continued compliance with the control requirements of the regulation. However, as an alternative to design documentation, an owner or operator would be allowed to document control device performance by source test results to show that the control device reduces organic emissions by the required percentage.

When carbon adsorption is used to remove organics from a gas stream, the carbon must periodically be replaced or regenerated when the capacity of the carbon to adsorb organics is reached. When either regeneration or removal of carbon takes place, there is an opportunity for organics to be released to the atmosphere unless the carbon disposal or regeneration is carried out under controlled conditions. There would be no environmental benefit in removing organics from an exhaust gas stream using adsorption onto activated carbon if the organics are subsequently released to the atmosphere during desorption or during carbon disposal. To avoid such an occurrence, today's proposal would require owners or operators using carbon adsorption systems for organic emissions control to take steps to ensure that proper emission controls are used during carbon regeneration or disposal.

For carbon adsorption systems using on-site carbon regeneration, the proposed standards would require that the determination of the carbon adsorption system organic reduction efficiency include not only organic emissions vented from the carbon bed but also the organic emissions vented from the carbon regeneration equipment. Regenerable carbon adsorption involves two separate steps. The first is the adsorption step during which the organic (adsorbate) is adsorbed on to the surface of the activated carbon (adsorbent). During the second step, the adsorbate is removed from the carbon (desorption) and recovered for reuse. Both of these steps are equally important in the overall process, and any organics released to the atmosphere in either step must be accounted for in the control device efficiency determination. For example, regeneration or desorption is usually accomplished by passing steam through the bed countercurrent to the vent steam flow. The steam carries the desorbed organics from the bed and is then condensed and decanted. Any organics that pass through the condenser (i.e., not condensed) and are vented to the atmosphere would need to be added to the quantity of organics vented from the carbon bed during the adsorption step to obtain the carbon adsorption system outlet organic emission rate for computing the control device organic removal efficiency. Similarly, if there are organics in the aqueous phase of the steam condensate that are not treated and eventually escape to the atmosphere, these must be added to the carbon adsorption system outlet organic emission rate.

For carbon adsorption systems that do not use on-site regeneration or require replacement of spent carbon, the proposed standards would require that the owner or operator certify that carbon removed from the system is either: (1) Regenerated or reactivated by a process that minimizes the release of organics to the atmosphere by using effective control devices such as those required in today's proposed rule, or (2) incinerated in a thermal treatment device that complies with the requirements of 40 CFR 264 subpart O.

E. Monitoring and Inspections

Monitoring and inspection requirements are included in the proposed standards to help ensure that emission controls are properly operated and maintained. Information provided by regular monitoring and inspections will enable owners and operators, as well as enforcement agencies, to determine whether emission controls are being operated properly and can be used as an indicator of compliance with the emission reduction efficiency requirements. In selecting monitoring and inspection requirements for today's proposed standards, EPA referred to approaches that are used in other EPA regulations that require the same or similar emission controls to those proposed today for TSDF tanks, surface impoundments, or containers. The frequency of the monitoring and inspection requirements in today's proposal have been selected to be consistent with existing requirements in 40 CFR parts 60, 61, and 264 to the extent that they are appropriate for TSDF units.

Monitoring is used here to refer to the measuring of specific control equipment operating parameters that have been selected as indicative of proper operation of the equipment. Inspections are visual observations of the overall control equipment condition to determine if there are any improper operating practices or equipment defects that could cause reduced control efficiency or allow the escape of organic vapors from the controlled unit.

1. Waste Management Units

Connections and seals on covers used to control organic emissions from waste management unit connections should not leak any organic emissions to the atmosphere provided they are properly installed and operated. Thus, the proposed standards require that cover connections and seals operate with "no detectable emissions". Control equipment is considered by EPA to be operating with no detectable emissions if there are no visible defects in the control equipment and the local volatile organic compound concentration is less than 500 ppm by volume (ppmv) at the surface of each seal or connection as determined by the procedure specified in Reference Method 21 "Determination of Volatile Organic Compound Leaks" in 40 CFR 60 appendix A. The Reference Method 21 was developed for the specific purpose of detecting organic

emissions from leaks. The 500 ppmv level used to define no detectable emission is separate and distinct from the waste volatile organic concentration level of 500 ppmw that is proposed for determining which waste management units would not be required to use organic emission controls. It is only a coincidence that the numerical value used for the two levels is the same.

The proposed standards would require the owner or operator to visually inspect covers used on affected tank, surface impoundment, and container units each week to check for evidence of visible defects. These inspections would serve to help ensure that the equipment is being used properly (e.g., hatches are closed and latched except when workers require access to a tank or container) and the equipment is being maintained in good condition (e.g., no holes or gaps have developed in covers). The inspection interval of once per week was selected so that the proposed inspection requirements could be included as part of the weekly inspections the owner or operator is already conducting to comply with existing RCRA standards (e.g., 40 CFR 264.195 for tanks, 40 CFR 264.254 for surface impoundments, 40 CFR 264.174 for containers).

To detect leaks around cover seals and fittings from openings too small to be detected by eye, initial and semiannual monitoring by Reference Method 21 would be required at all connections and seals on each cover. The monitoring would be required to be performed during loading of waste into the unit or, for nonquiescent waste management processes, while the unit is generating emissions.

If the inspection or monitoring of a component inspection indicates that the emission control equipment requires repair, the proposed regulation would require that an initial attempt at repair of the equipment be performed as soon as possible but no later than 5 calendar days after detection of the leak and that the repair work be completed within 15 calendar days. It is EPA's intention that the owner or operator promptly repair emission control equipment components. The EPA also recognizes that under some circumstances a repair of emission control equipment cannot always be made upon leak detection because facility maintenance personnel are not immediately available, the replacement part necessary to repair the equipment is not stocked in the facility's on-site spare parts inventory, or special contractors must be hired to perform the repair work. However, regardless of the circumstances, EPA expects the owner or operator within the first 5 calendar days following detection of the leak to, at a minimum, take initial actions to complete the repair (e.g., tighten cover gasket fittings, replace cover seals, patch cover membrane material), schedule facility maintenance personnel or control equipment vendor service personnel (if special repair work is needed), and order replacement parts (if needed). If repairs cannot be completed within the 15 calendar day period, the owner or operator would not be allowed to add waste to that unit until the repairs were completed.

One exception to the 15 calendar day repair period is being proposed today. An extended repair period beyond 15 calendar days would be allowed for surface impoundment covers under certain conditions. It is EPA's understanding that a surface impoundment may occasionally be a critical component of a company's manufacturing process (e.g., there is no backup or alternative waste management unit available for placing the hazardous waste generated by the manufacturing process). Also, performing some types of repairs on the surface impoundment cover may require the surface impoundment first be drained so that the entire manufacturing process would need to be shut down until the repairs were completed. Shutdown of an entire manufacturing process could possibly create a substantial hardship and significant economic losses for a company. To avoid this situation without diminishing the protection of human health and the environment provided by the standards, EPA concluded that if delaying the repair of the surface impoundment cover would not cause the emission controls to be significantly less protective, then it would be appropriate to allow continued use of the surface impoundment but delay the repair of the surface impoundment cover until the next time the manufacturing process is shut down either for scheduled maintenance or because of a process breakdown or upset. Therefore, EPA is proposing that the repair period for a surface impoundment cover may be extended beyond 15 calender days until the next time the process that generates the waste which is placed in the surface impoundment is shut down, provided the owner or operator documents that the repair cannot be completed without a process shutdown and that delaying the repair would not cause the emission controls to be significantly less protective. The EPA requests comment on the need to provide this extended repair period for certain surface impoundment cover applications.

2. Closed Vent Systems and Control Devices

Closed vent systems and control devices used to control emissions from waste management units would be required to be periodically inspected and monitored to insure that they are operated and maintained in accordance with their design. The proposed standards would require that closed vent systems and control devices be visually inspected at least once per week. Each closed vent system would need to be monitored for detectable emissions using Reference Method 21 at least once per year. Monitoring of a closed vent system could be required at other times requested by the Regional Administrator. If an instrument reading indicated detectable emissions, then the owner or operator would be required to initiate repair of the system within 5 calendar days after detection and to complete the repair no later than 15 calendar days after detection.

The proposed standards would require the owner or operator to install, calibrate, maintain, and operate monitors that continuously measure and record specific control device operating parameters. The monitoring would be required to be performed in accordance with the requirements that have been promulgated by EPA under 40 CFR 264 subpart AA (specifically § 264.1033(f)–(h)) for monitoring the performance of control devices used to reduce organic emissions from TSDF process vents. The parameters to be monitored vary depending on the type of control device used. For thermal vapor incinerators, continuous monitoring of combustion zone temperature would be required. For boilers and process heaters having a design heat input capacity less than 44 MW, continuous monitoring of combustion zone temperature would be required. For boilers and process heaters having a design heat input capacity equal to or greater than 44 MW, continuous monitoring of a parameter that indicates good combustion operating practices are being used would be required. For catalytic vapor incinerators, continuous monitoring of temperature upstream and downstream of the catalyst bed would be required. For flares, continuous monitoring of visible emissions and pilot flame ignition would be required. For carbon adsorption systems that regenerate the carbon bed directly in the control device such as a fixed-bed carbon adsorber, continuous monitoring of exhaust gas organic concentration or

a parameter that indicates that the carbon bed is regenerated or replaced at regular, predetermined intervals would be required. For condensers, continuous monitoring of coolant fluid exit temperature and exhaust gas temperature would be required. These monitoring parameters were selected on the basis of previous analyses performed for EPA rulemakings under the Clean Air Act for the synthetic organic chemical manufacturing industry that showed that these parameters are indicative of control device performance. For control devices not otherwise specified, monitoring parameters would be specified in the design plan and the limits would be established during a performance test. The standards would also require that control device monitoring data be reviewed by the owner or operator at least once each day the control device is in operation to ensure that the device is operating properly (i.e., operating at design specifications).

Continuous monitoring of a carbon adsorption system that does not regenerate the carbon directly on-site in the control device such as a carbon canister would not be required by today's proposed standards. Carbon canisters are simple, low-cost control devices that would likely be applied to individual tanks or other sources venting low volume and flow rate vapor streams. Application of continuous monitors to these types of carbon adsorption systems would not be reasonable because the cost of using continuous organic monitors would be expensive relative to the cost of the control device. A less expensive approach which achieves the same purpose is for the owner or operator to replace the carbon in the control device with fresh carbon on a regular basis before carbon breakthrough occurs. Therefore, the proposed standards would require that the replacement interval be determined in accordance with § 264.1033(h) by either periodic monitoring of the organic concentration level in the exhaust vent stream from the control device or by design calculations.

F. Recordkeeping Requirements

The proposed standards would require that certain data and records be routinely reviewed and be entered into the facility operating record required by 40 CFR 264.73 and 40 CFR 265.73. Because these sections do not apply to hazardous waste generators, hazardous waste generators affected by the proposed standards (i.e., large quantity generators using 90-day accumulation tanks or containers) would be required to maintain the specified data and records in a file located on-site that would be readily available to EPA or authorized State personnel. The information to be maintained on-site includes the following items: the results of all waste analyses for volatile organic concentration and organic vapor pressure; information pertaining to closed vent system and control device design as described in 40 CFR 264 subpart BB; design and monitoring data for covers and enclosures; all control device exceedances and the actions taken to remedy them; and all inspection records. Consistent with §§ 264.73 and 265.73, the proposed standards would require that all records be maintained in the facility operating record until facility closure except records and results of inspections and monitoring, which would need to be kept for 3 years from the date of entry.

In selecting the recordkeeping requirements, EPA wanted to ensure that adequate information is available to owners and operators as well as to enforcement agencies to verify that control systems are being properly operated and maintained. The EPA was also seeking to avoid placing undue burden on owners and operators with unnecessary monitoring and recordkeeping requirements. The EPA believes that the selected procedures are adequate and that the monitoring and recordkeeping burden is reasonable. Required records must be furnished to EPA upon request and must be readily available for inspection by EPA or authorized State representatives at all reasonable times.

G. Reporting Requirements

The proposed standards would require an owner or operator of a permitted TSDF (i.e., a facility subject to 40 CFR part 264) to submit reports to EPA only when events occur at the TSDF that result or may result in the facility being in noncompliance with certain requirements of the proposed standards. No reporting requirements are proposed for interim status TSDF (i.e., a facility subject to 40 CFR part 265).

An exception from certain proposed control requirements would be allowed for a tank, surface impoundment, or containers subject to the standards, provided the volatile organic concentration of the waste placed in the unit is below 500 ppmw. The EPA intends that this exception apply only to those units for which the owner or operator can be reasonably certain that the volatile organic concentration of the waste consistently remains below 500 ppmw. Failure to use the required organic emission controls on units into which waste with volatile organic concentrations of 500 ppmw or more are placed would be noncompliance with the standards. Therefore, in the event that a waste exceeding the 500 ppmw volatile organic concentration limit is placed in a unit without the specified emission controls, the owner or operator would be required to submit a report to EPA explaining the reasons why the waste could not be managed in compliance with the requirements of the standards. The owner or operator would be allowed up to 30 calendar days after a waste determination is performed to prepare and submit the report to EPA.

Under the proposed standards, the owner or operator would be required to properly operate and maintain each control device used to comply with the standards. Also, as previously described, the proposed standards would require continuous monitoring of specific control device operating parameters. A control device monitor reading outside the operating range allowed by the standards indicates that the control device is not operating normally or is malfunctioning (i.e., not operating at the design setting necessary to achieve at least 95 percent organic emission control efficiency), and action must be taken by the owner or operator to return the control device to operation at the design setting. When a control device malfunction cannot be corrected within 24 hours of detection (referred to in this preamble as a "control device exceedance"), the proposed standards would require the owner or operator to record additional information about the control device exceedance. This information would then be reported to EPA on a semiannual basis. The report would need to describe the nature and period of each control device exceedance and to explain the reason why the control device could not be returned to normal operation within 24 hours. A report would need to be submitted to EPA only if control device exceedances have occurred during the past 6-month period. These reports aid EPA in determining the owner's or operator's ability to properly operate and maintain the control device. The EPA recognizes that a control device malfunction may occur due to circumstances beyond the control of the owner or operator (e.g., defective equipment supplied by the manufacturer). Therefore, a single control device exceedance may not necessarily be indicative of improper control device operation or maintenance.

H. Alternative Standards for Tanks

To provide some owners or operators of TSDF tanks with additional flexibility in complying with today's proposed standards, owners and operators would be allowed to use as an alternative to a cover vented to a control device either: (1) A fixed roof with an internal floating roof, (2) an external floating roof, or (3) an emission control for which a Federal Register notice has been published in accordance with 40 CFR 60.114(b). The alternative emission control would not be suitable for all TSDF tanks for several reasons. First, floating roofs are only suitable for vertical, smooth wall tanks with sufficiently large diameters. Also, floating roofs cannot be used for TSDF tanks where the presence of the floating roof would interfere with a treatment process (e.g., tanks equipped with surface mixing or aeration equipment). Finally, because the floating roof deck and seals are in direct contact with the hazardous waste, the materials used to fabricate these components must be compatible with the waste composition to obtain a reasonable equipment service life. Thus, EPA expects that the alternative standards for tanks will primarily be used for some but not all large TSDF tanks storing liquids with a volatile organic content greater than 500 ppmw.

Special inspection, monitoring, recordkeeping, and reporting requirements for internal and external floating roofs would be required by today's proposal because TSDF workers and EPA enforcement personnel cannot see inside a tank equipped with these types of control equipment unless the tank is empty. These requirements are selected to be consistent with the inspection, monitoring, recordkeeping, and reporting requirements now being implemented by EPA under the Clean Air Act for New Source Performance Standards (NSPS) for volatile organic liquid storage (40 CFR 60 subpart Kb). The EPA believes that the tanks affected by the NSPS (i.e., liquid storage tanks containing varying amounts of organics) are sufficiently similar to the TSDF tanks expected to use floating roofs to justify the same inspection, monitoring, recordkeeping, and reporting requirements.

1. Standards

The alternative standards proposed today for internal and external floating roofs are identical to the requirements specified in the existing NSPS for volatile organic liquid storage (40 CFR 60 subpart Kb). For internal floating roofs, the closure devices must be a foam- or liquid-filled seal, two continuous seals, one above the other, or a mechanical shoe seal. For external floating roofs, the closure device must consist of two continuous seals, a primary seal and a secondary seal, one above the other.

Today's proposal does not contain the provision in the NSPS for volatile organic liquid storage that allows a tank owner or operator to petition the EPA for a determination of equivalency of an emission control not specifically identified in the regulations. However, if an emission control is determined to be equivalent by EPA for tanks subject to the NSPS under the provisions of 40 CFR 60.114(b), then that type of emission control would be acceptable for use on a TSDF tank in order to comply with the standards proposed today.

2. Special Inspection Requirements

The special inspection and monitoring requirements for internal and external floating roofs would require an initial inspection of the primary and secondary seals at the time the roof is installed. Subsequent inspections would be required to be performed at intervals ranging from 1 to 5 years depending on the type of seal mechanism used. Inspection of internal floating roofs would be by visual inspections to ensure that no holes, tears, or gaps develop in the seals. Inspections of external floating roofs would require measurement of gap widths between the primary seal and the wall, and between the secondary seal and the wall to ensure that these gaps are maintained within specified limits.

3. Special Recordkeeping Requirements

The special recordkeeping requirements for internal and external floating roofs would require the owner or operator to maintain certain records in the facility operating records. Documentation would be required that describes the internal floating roof or external floating roof design and certifies that the control equipment meets the specifications listed in the regulation. If the inspection of an internal floating roof identifies any defects, a description of the nature of the defects, and the date and means by which repair was made would need to be placed in the operating records. For external floating roofs, the records for the seal gap monitoring would need to include the date of the measurements, the raw data from the measurements, and the calculations of gap area as specified in the standards. If the measurements identify gaps exceeding specified limits, the records would also need to describe the gap area calculations and the date and means of repair. Consistent with § 264.73 and § 265.73. the proposed standards would require that all records be maintained in the facility operating record until facility closure except records and results of inspections, which would need to be kept for 3 years from the date of entry.

4. Special Reporting Requirements

The special reporting requirements for internal and external floating roofs would require the owner or operator subject to the standards in 40 CFR part 264 to notify EPA in writing at least 30 days prior to the filling or refilling of a tank to provide EPA the opportunity to inspect the roof and seals for compliance with the standards. This requirement is necessary because the roof seals can only be inspected when the tank is empty.

I. Standards for Miscellaneous Units

The EPA has promulgated standards in 40 CFR part 264 for specific types of waste management units. These standards serve not only to regulate the operation of these units at TSDF but also to provide a basis for evaluating the issuance of permits to operate these units. So that owners and operators can obtain permits to operate hazardous waste management technologies that are not covered elsewhere under part 264, EPA promulgated standards under 40 CFR 264 subpart X which apply to "miscellaneous units" (52 FR 46946). A "miscellaneous unit" is defined in 40 CFR 260.10 as a hazardous waste management unit where waste is treated, stored, or disposed of that is not a container, tank, surface impoundment, waste pile, land treatment unit, landfill, incinerator, boiler, industrial furnace, underground injection well with appropriate technical standards under 40 CFR part 146, or a unit eligible for a research, development, and demonstration permit under 40 CFR 270.65.

Miscellaneous units are permitted on a case-by-case basis with terms and provisions as needed to protect public health and the environment through generic performance standards specified in 40 CFR 264.601. Section 264.601 requires that appropriate portions of the existing requirements be incorporated into the permit (subparts I through O at the time subpart X was promulgated). For example, in regulating air emissions from a pyrolysis unit (a type of unit not covered by specific standards in part 264), the permit for the unit would incorporate the applicable requirements of the subpart O incinerator standards. Because it is EPA's intention that all existing air and water environmental

standards be considered for issuance of a permit for a miscellaneous unit, it is appropriate to amend subpart X at this time to include the air emission standards that have been developed since subpart X was promulgated. Therefore, today's proposed standards would amend 40 CFR 264.601 to require that permit terms and provisions for a miscellaneous unit being permitted under 40 CFR part 264 subpart X include the appropriate air emission control requirements promulgated in subparts AA and BB of 40 CFR part 264, and proposed today as subpart CC of 40 CFR part 264.

Application of the subpart CC standards to miscellaneous units would require determining which one of the waste management unit categories (i.e., tank, surface impoundment, or container), if any, is most similar to the miscellaneous unit. For example, waste is sometimes stored or treated in units consisting of a flexible, synthetic liner supported by an above-ground metal frame (instead of a depression formed of earthen materials as is the case for a surface impoundment). Similar to a surface impoundment, the placement of wastes containing more than 500 ppmw volatile organics in this unit would result in significant organic emissions from the exposed waste surface. Likewise, using the same type of emission controls applicable to surface impoundments (e.g, floating membrane cover) would reduce organic emissions. Therefore, in this case where the miscellaneous unit is determined to resemble a surface impoundment, a subpart X permit may be issued that would include relevant provisions of the subpart CC surface impoundment standards being proposed today.

VIII. Generator Accumulation Tanks and Containers Emission Controls

Hazardous waste generators who accumulate waste on-site in containers or tanks for short periods of time are specifically exempted from the RCRA subtitle C permitting requirements provided the generators comply with the provisions specified in 40 CFR 262.34. Both large quantity generators (i.e., generators who generate more than 1,000 kilograms per calendar month) and small quantity generators (i.e., generators who generate more than 100 kilograms but less than 1,000 kilograms per calendar month) can be exempted. A large quantity generator is exempted if hazardous waste is accumulated on-site in tanks and containers for 90 days or less and certain requirements are met as specified in§ 262.34(a) including compliance with 40 CFR part 265 subpart I (if the waste is accumulated in a container) or subpart J (if the waste is accumulated in a tank). The generator accumulation tanks and containers that meet these requirements are referred to in this preamble as "90-day tanks and containers." A small quantity generator is exempted if hazardous waste is accumulated on-site in containers and tanks for up to 180 (or 270 days in some cases) and certain requirements are met as specified in 40 CFR 262.34 (d) and (e) including compliance with container requirements in 40 CFR 265 subpart I and with special tank requirements in 40 CFR 265 subpart J (specifically § 265.201). All generators are exempted for containers used at or near the point of generation to accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 CFR 261.33(e) provided certain requirements are met as specified in 40 CFR 262.34(c).

In most cases, 90-day tanks and containers are used by large quantity generators to accumulate waste upon generation, and may handle waste before it is managed in on-site waste management units that require RCRA permits or before it is shipped off-site for management at a commercial TSDF. As a result, if these 90-day tanks or containers are open to the atmosphere, a significant fraction and possibly all of the volatile organics contained in the waste may be volatilized and lost to the atmosphere before the waste is managed in a waste management unit that is controlled for air emissions. If this were to occur, a substantial portion of the organic emission and cancer risk reductions that could potentially be achieved by implementation of the proposed standards would remain unrealized.

In view of the organic emissions potential of 90-day tanks and containers, EPA evaluated the health and environmental impacts of emissions from these accumulation units. Data from a 1986 survey of hazardous waste treatment, storage, disposal, and recycling facilities, a 1981 survey of hazardous waste generators, and a 1985 survey of small quantity generators were used as the basis for the analysis. The most recent 1986 survey data only accounted for 90-day tanks and containers located at a TSDF site. Therefore, these data were supplemented by the results of the 1981 generator survey to estimate nationwide numbers of 90-day tanks and containers. The results of the 1985 survey of small quantity generators were used to estimate nationwide numbers of accumulator units at small quantity generators.

The survey data were used as the basis for estimating the environmental and health impacts of organic emissions from 90-day tanks and containers and the costs associated with controlling these emissions. The estimates were made using the same analytical approach used to estimate organic emissions, health impacts, and control costs for TSDF tanks, surface impoundments, and containers described in section III. A detailed description of the 90-day tank and container impacts estimate procedure is provided in Appendix L of the BID.

The analysis results estimate that nationwide emissions of organics from 90-day tanks and containers are approximately 259 thousand Mg/yr under baseline conditions. Annual cancer incidence as a result of exposure to these emissions is estimated to be approximately 21 cases per year. It was further estimated that if the air emission control requirements being proposed for tanks and containers at TSDF were also applied to 90-day tanks and containers, nationwide annual emissions of organics from 90-day tanks and containers would be reduced to approximately 4 thousand Mg/yr and the annual cancer incidence would be reduced to less than 1 case per year. The capital costs of adding emission controls to 90-day tanks and containers are estimated to be approximately $41 million. Total annual costs are estimated to be approximately $8.6 million for 90-day tanks and containers.

The estimated health and environmental impacts of 90-day tank and container emissions can be interpreted in two ways. If the waste analyses used as a basis for estimating emissions and incidence from permitted units are assumed to represent the waste at the time it enters the permitted unit, then the impacts estimated for 90-day tanks and containers are separate from, and in addition to, the impacts estimated for permitted units. On the other hand, if the waste analyses used to estimate emissions from permitted units represents the waste near the point where it is generated, and if the 90-day tanks and containers are one of a series of waste management activities through which the waste passes between the point of generation and the point of final disposition, then the impacts estimated for 90-day tanks and containers do not represent separate impacts in addition to those estimated for permitted units. Instead, emissions estimated from 90-day tanks and containers would double count the emissions estimated from permitted units and, to the extent that this situation exists, the emissions and

emission reductions estimated for permitted units would be overstated.

Waste data used in the analysis of permitted units, which served as the basis for the above analysis, were based on analyses of waste samples taken both at the point of generation and at the waste management unit. Because the data used in the analysis represent the waste at different points in the waste management sequence, the actual impacts of 90-day tanks and containers are probably somewhere between the two situations cited. Although EPA currently does not have sufficient information to make accurate estimates of the relationship between emissions from permitted units and 90-day tanks and containers, the survey data indicate that approximately 70 percent of the waste managed in 90-day tanks and containers is subsequently managed in permitted units. Thus, it can be stated with relative assurance that at least 30 percent of the estimated health and environmental impacts for 90-day tanks and containers are in addition to the impacts for permitted units. Regardless of the exact magnitude of emissions from 90-day tanks and containers, EPA is convinced that if these units are allowed to operate without air emission controls, the health and environmental impacts would be substantial and may undermine the predicted benefits of today's proposed regulation as applied to permitted units.

Impact estimates were also performed for small quantity generators. At small quantity generators, baseline annual emissions of organics are estimated to be approximately 2,000 Mg/yr, and annual cancer incidence is estimated to be approximately 0.16 case per year. With the use of the proposed organic emission controls, estimated emissions would be reduced to approximately 100 Mg/yr, and cancer incidence would be reduced to less than 0.01 case per year. Control cost estimates for small quantity generators were based on the small quantity generator survey data which indicated that most affected units at these sites would be quiescent and thus would require only covers to control emissions. A small fraction of units are nonquiescent and would be required to install covers and control devices to comply with the proposed standards. The capital costs of controlling small quantity generators are estimated to be about $13 million. Total annual costs are estimated to be approximately $4.9 million for small quantity generators.

Because of the large emission potential of the 90-day tanks and containers located at TSDF and large quantity generators, EPA is proposing that 90-day tanks and containers located at TSDF and large quantity generators be included in the air emission sources regulated by today's proposed standards. The EPA has decided not to include accumulation tanks and containers at small quantity generators in today's proposed regulation because of the relatively small organic emission potential for an estimated large number of facilities (approximately 54,000) that would be affected. The EPA may decide to regulate accumulation tanks and containers used by small quantity generators at some future date if new information becomes available that suggests different impacts from those estimated by the current evaluation.

Another group of accumulation containers, referred to as "satellite accumulation units," is not included in today's proposed rule. The provisions of § 262.34 describing satellite accumulation allows generators to accumulate up to 55 gallons of hazardous waste in a container without complying with subpart I of 40 CFR 265 if the containers are at or near the point where waste initially accumulates, and if the accumulation is performed under the responsibility of the operator of the waste generating process. Satellite accumulation may occur over any length of time without having to comply with the other provisions of § 262.34 related to 90-day tanks and containers. The provisions related to satellite accumulation were added as an amendment to § 262.34 because of the small quantities of waste involved and the large number of sites at which satellite accumulation may occur at industrial facilities. The EPA believes that the rationale for excluding satellite accumulation from the regulations covering 90-day tanks and containers is equally valid for excluding them from the requirements of today's proposal. Thus, satellite accumulation units are not included in the sources regulated by today's proposed standard.

Today's proposal would amend subparts I and J of 40 CFR 265 to add a requirement that 90-day tanks and containers covered by these subparts would also have to comply with air emission control requirements in subparts AA, BB, and CC. The permit-exempt status of units complying with 40 CFR 262.34 would be maintained. The decision to apply air emission regulations to 90-day tanks and containers was made after the standards for process vents (subpart AA) and equipment leaks (subpart BB) were proposed. However, the rationale that served as the basis for regulating process vents and equipment leaks at TSDF is also applicable to process vents and equipment leaks associated with 90-day tanks and containers. That is, the emission mechanisms and control technologies are the same for process vents and equipment leaks at TSDF as they are for process vents and equipment leaks associated with 90-day tanks and containers. Consequently, today's rulemaking also proposes that 90-day tanks and containers must also comply with the air emission standards in subparts AA and BB in addition to subpart CC.

IX. Test Methods

This section discusses the two test methods being proposed today: (1) Reference Method 25D' "Determination of the Volatile Organic Concentration of Waste Samples," used to determine the waste volatile organic concentration; and (2) Reference Method 25E, "Determination of Vapor-Phase Organic Concentration in Waste Samples," used to determine which wastes may be placed in tanks with covers only rather than tanks with covers and vented to a control device. The purposes of each of these methods and their intended uses are described in more detail in the following paragraphs.

A. Waste Volatile Organic Concentration Test Method

1. Background

The proposed organic emission controls are not required to be used on an affected waste management unit if an owner or operator determines that the waste being managed in the unit has a volatile organic concentration less than 500 ppmw. This determination may involve testing of wastes to determine volatile organic concentration. A new test method designated as Reference Method 25D, "Determination of the Volatile Organic Concentration of Waste Samples," is being proposed for this purpose in 40 CFR part 60, Appendix A. The identical test method would also be added to "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication No. SW-846) as Test Method 5100.

In seeking to identify a method for determining the volatile organic concentration of a waste, the EPA evaluated several candidate test methods. Objectives of the evaluation were to identify a test method whose results determine the volatilization potential of the waste, including retention of the volatiles in the waste whose results are reproducible, and that is relatively simple and easy to use. The method also needed sufficient

sensitivity to detect organic concentrations as low as 100 ppmw in the waste.

Methods based on separation of the volatile fraction from the waste matrix by equilibrium headspace analyses, steam distillation, and nitrogen purging were evaluated in a laboratory program. Reports on method development work were distributed for review by the public on February 4, 1987, and April 5, 1988. Initially, it appeared that a method using steam distillation would be the most appropriate. However, based on review of public comments received on the test method development reports and additional analyses, EPA selected a heat and nitrogen purge method for proposal. The proposed test method is based on procedures judged to yield good retention of volatiles during sample preparation. It is also judged to separate fewer relatively nonvolatile compounds from the waste samples than the steam distillation process, therefore yielding a better determination of volatilization potential. The proposed test method is also easier to use than the steam distillation process. The waste volatile organic content test method discussion is broken into the following sections: (1) Sampling, (2) liquid matrix for sample analyses, (3) purge conditions, (4) analytical detectors, and (5) method application.

In summary, the proposed test method requires representative samples to be taken before the waste is exposed to the atmosphere where volatiles can be lost. Each sample is transferred to a container holding polyethylene glycol (PEG) to prevent loss of volatiles. The samples are cooled and sent to the laboratory for analysis. In the laboratory, water is added to the PEG/sample mixture and that mixture is heated and purged with a stream of nitrogen (6 liters per minute at 75 °C). The purged gas stream is sent through detectors that measure the quantity of organic carbon and halogens removed from the waste. The mass of the total organic carbon, calculated as methane, and halogens, calculated as chloride, are converted by calculation to a concentration by weight of volatile organics.

The proposed test method would require the analysis of an audit sample obtained through the appropriate regulatory agency. An audit material has been developed in order to identify and quantify laboratory bias in the analysis portion of the method. The audit sample is formulated to resemble an actual waste sample, and would be analyzed according to the test procedure.

The rationale for the test method is described below.

2. Sampling

In the proposed test method, the sampling procedure is designed to assure that the sample is representative of the waste stream and to minimize the loss of volatiles during sample preparation. Representative samples are obtained by using appropriate sample collection procedures, which include sampling as close as possible to the point of generation (before the waste is exposed to the atmosphere where volatiles can be lost), and sampling, whenever possible, from an enclosed pipe.

The proposed method requires a static mixer to be used in the sampling line to reduce stratification and provide a well mixed stream for sampling. However, the EPA recognizes static mixers may not be appropriate for some streams, and that they may not be the best way to deal with stratification in some streams being sampled. The EPA requests comments in the use of and need for static mixers or alternate procedures to achieve a representative sample.

Loss of volatiles is minimized by cooling the sample, collecting it directly into PEG, and minimizing sample transfers. Grab samples are collected using pre-cooled sample containers that have been completely filled with PEG except for a volume equivalent to the 10 milliliter sample size. When a sample is collected, a sample container is opened, and the sample is injected into the sample container beneath the surface of the PEG to minimize exposure to the atmosphere. After the sample is transferred into the container, the container is immediately capped and cooled for transfer to the laboratory for analysis. In the laboratory, the sample is transferred to the purge container, and water is added to the purge container.

3. Liquid Matrix for Sample Collection and Analyses

The PEG and water medium was selected as the liquid matrix from which the volatile organics are purged after considering water, dioctylphthalate (DOP), DOP/water PEG, and PEG/water matrices during development of the test method. Use of an organic in the matrix was concluded to be essential in order to reduce the loss of volatiles after the sample collection. Therefore, water alone would not be a suitable medium. Comments received from industry identified several problems with the use of DOP, including the potential for source organics to react with DOP and the overestimate of emission potential of organics such as phenol (relatively nonvolatile) when mixed with DOP. Therefore, DOP was eliminated as a suitable medium. The PEG and water matrix was selected over PEG alone to better estimate emission potential of certain compounds having relatively high Henry's Law constants, but medium to low vapor pressures such as dichlorobenzene, napththalene, and tetrachloroethylene.

4. Purge Conditions

For the proposed method, the sample/PEG/water mixture is heated to 75°C and purged with nitrogen (6 liters per minute) for 30 minutes. Ranges of purge rates and purge temperatures were investigated during method development. A purge gas temperature of 75°C and a purge gas rate of 6 1/min were selected to provide the best measure of emission potential because it is a compromise between the goal of purging and measuring those compounds that tend to volatilize over the longer term, and the goal of not purging and therefore not measuring the relatively non-volatile compounds.

5. Analytical Detectors

The proposed method produces a generic volatile organic concentration measurement without identifying the specific organic compounds present in the waste. Carbon and halogens have been selected as the elements measured by analytical detectors to determine the organic concentration by weight. The measurement of carbon is essential as it is the best indicator of the presence of organics. However, the measurement of the mass of carbon in the sample only provides a portion of the mass for many organic compounds. Therefore, selection of other elements for measurement was considered as well to provide a basis to estimate the true weight of the organics present in the waste sample. Halogens were selected because of their relatively high molecular weight as compared to carbon and because of their prevalence (especially chlorine) in organic compounds widely managed in hazardous waste TSDF. Other elements, such as oxygen, nitrogen, and sulfur, are also candidates for measurement because of their presence in organic compounds. They have not been selected at this time because to do so would greatly increase the complexity of the test method without greatly improving the accuracy of the test method.

6. Method Application

Two bleed streams are split from the heated purge gas stream as it leaves the purge chamber. One bleed stream is directed to a flame ionization detector

(FID), where the organic carbon is measured, while the other is directed to an electrolytic conductivity detector (ELCD), where halogens are measured. Both the FID and the ELCD results are integrated over the purge period and, coupled with the measured flow rates, provide a measure of the amount of total organic carbon and the total halogens, respectively, removed from the waste sample. The quantity of organic carbon, calculated as methane, and the quantity of halogens, calculated as chloride, removed with the purge gas are used to determine the concentration of volatile organics in the original waste sample. Methane is used as the basis for reporting carbon in the concentration calculation to account for the weight of hydrogen and other elements typically present in organic compounds, but not detected by either the FID or ELCD. Chloride was selected as the basis for reporting halogens in the concentration calculation because it is the prevalent halogen present in wastes.

B. Waste Vapor-Phase Organic Concentration Test Method

Today's proposal allows certain tanks used for quiescent waste management processes to use only a cover provided that the tank volume is less than a specified size, or, if the volume is larger than the specified size, the owner or operator determines that the wastes managed in the tank have an organic vapor pressure less than a specified pressure. The determination of waste organic vapor pressure requires testing of the waste to be managed in the tank to measure the waste vapor-phase organic concentration. A test method for this purpose, designated as Reference Method 25E, "Determination of Vapor-Phase Organic Concentration in Waste Samples," is being proposed today for addition to 40 CFR part 60 appendix A. An identical test method would also be added to "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication No. SW-846) as Test Method 5110. Several alternative methods would also be acceptable including methods described in American Petroleum Institute Bulletin 2517, "Evaporation Loss From External Floating Roof Tanks: ASTM Method D2879-83" as modified for use with this proposed rule.

The EPA considered several candidate methods to measure the vapor-phase organic concentration of the waste or waste organic vapor pressure. The objectives of the selection process were to identify a test method that is related to the volatilization potential of the waste, that gives results that are reproducible, that is relatively simple, and is easy to use. In this case, i.e., the matter of exception from the requirement for a control device on a covered tank, the volatilization potential and hence the emission potential of the waste in the covered tank is related to the vapor-phase organic concentration or waste organic vapor pressure.

Several candidate organic vapor pressure methods considered are used for other tanks storing volatile organic and petroleum liquids in the synthetic organic chemical manufacturing industry (SOCMI) and the petroleum refining industry. Those other tanks are presently regulated under the Clean Air Act (40 CFR 60 Subparts Ka and Kb). These methods are: (1) A method described in American Petroleum Institute Bulletin 2517, "Evaporation Loss From External Floating Roof Tanks," and (2) ASTM Method D2879-83 (modified for use with this proposed rule). Many of the wastes that would be regulated by today's proposed rule have significant aqueous fractions, and water vapor from the aqueous fraction interferes with (adds to) the direct measurement of waste vapor pressure. The direct vapor pressure measurement methods would, therefore, tend to produce higher vapor pressure results than only measuring the vapor pressure of the waste's organic fraction. The direct pressure measurement methods could be satisfactorily applied to those wastes that are predominantly non-aqueous, however.

In considering the ASTM Method D2879-83 direct vapor pressure measurement method for use with today's proposed rule, the EPA believes that it is necessary to modify the method to eliminate the procedure that allows the sample to be degassed by reducing the system pressure and heating the liquid prior to the vapor pressure measurement. The concern is that the degassing step may drive off the compounds whose vapor pressure the method is intended to measure, especially for wastes with relatively low concentrations of volatile organics. The EPA is interested in receiving comments from the public on this matter. The above candidate vapor pressure measurement methods may be used by the owner or operator at their discretion, but are not recommended for determining aqueous waste organic vapor pressure because of positive bias introduced by water vapor.

The approach used in the proposed test method is to collect a waste sample at the tank inlet in a headspace sample vial and transfer the vial to a balanced pressure headspace sampler, which pressurizes the sample vial and injects a vapor sample into the FID for analysis of organic carbon. In the proposed test method, the sampling procedure to obtain representative samples and prevent loss of volatiles is much the same as described above for Reference Method 25D.

Helium is used to pressurize the sample vial, and the pressure is released to transfer a headspace sample directly into the FID's gas sample loop. The headspace sample is injected directly into the FID from the sample loop, and the FID response is used to measure the concentration of organic carbon in the vapor sample as propane. This vapor-phase organic concentration (expressed as propane) is then converted, by a calculation given in the method, to waste organic vapor pressure.

To calculate organic waste vapor pressure from the measurement of carbon, it is necessary to assume the number of carbon atoms associated with each mole of gas in the vapor-phase. The selection of propane as the compound for the basis of the vapor pressure calculation was made after studying a list of 53 organic compounds with vapor pressures in excess of 1.3 kPa that are found in waste. A study of the compound list showed that the arithmetic average number of carbon atoms in the compounds was 2.8. Thus, propane with three carbon atoms was designated as the compound basis for the conversion calculation. The effect of using propane as the basis is to overestimate the organic vapor pressure if the compounds in the vapor-phase are mostly C_4 or higher compounds, and to underestimate the organic vapor pressure if the vapor-phase compounds are predominantly C_2 or C_1 compounds. Of the 53 compounds studied, 39 had three or fewer carbon atoms. The EPA is interested in receiving comments from the public on the proposed method, and particularly the selection of propane as the basis for the vapor pressure calculation.

X. Implementation

A. Implementation of Rules at Permitted TSDF

1. Background

New RCRA standards (such as today's proposal) typically apply to interim status facilities on the effective date of the standards. In the case of permitted facilities, however, new standards generally do not apply until the facilities' permits are modified or renewed. This practice is often referred to as the "permit-as-a-shield." Under the current RCRA permitting system, a facility that has received a final permit

must comply with all of the following requirements as specified in 40 CFR 270.4: (1) The specific conditions written into the permit (including conditions that demonstrate compliance with Part 264 regulations); (2) self-implementing statutory requirements; and (3) regulations promulgated under 40 CFR Part 268 restricting the placement of hazardous waste in or on the land. When new regulations are promulgated after the issuance of a permit, EPA may reopen the permit to incorporate the new requirements as stated in § 270.41. Otherwise, the new regulatory requirements are incorporated into a facility's permit at the time of permit reissuance, or at the five year review for land disposal facilities.

Although EPA has the authority to reopen permits to incorporate the requirements of new standards, EPA is concerned about the resource burdens of this approach. To reopen permits for each new regulation at the time it is promulgated would impose a large administrative burden on both EPA and the regulated community as each permit modification would generally require the same administrative procedures as are required for initial permits (e.g., development of a draft permit, public notice, and opportunity for public hearing). As a consequence, the requirements of new standards are usually incorporated into a permit when it is renewed.

In today's rule, EPA is proposing to remove the permit-as-a-shield provision as it applies to control of air emissions under RCRA Section 3004(n). Thus, the proposal to remove the permit-as-a-shield provision would affect the implementation of the standards proposed today for organic emissions from tanks, surface impoundments, and containers, and the air emission standards recently promulgated for vent and equipment leak emissions (55 FR 25454). This is the first major group of air emission standards to be developed under RCRA (excluding incinerator standards). Accordingly, with the development of these standards EPA evaluated the need to implement the TSDF air standards at permitted facilities more quickly than would be done under the current regulatory policy. In this evaluation, a variety of factors was considered, including the extent of the environmental and health impacts of TSDF emissions, Congressional intent, and ease of implementation. These factors are discussed below.

2. Extent of Health and Environmental Impacts

As discussed in Section V, baseline excess cancer incidences resulting from nationwide TSDF organic emissions are estimated to be 140 cases per year and the maximum individual risk (MIR) is approximately 2×10^{-2}. In addition, organic emissions from TSDF account for more than 10 percent of total nationwide organic emissions from stationary sources and thus contribute significantly to the formation of atmospheric ozone. These health and environmental impacts are very high relative to the impacts of releases from other sources regulated under RCRA and the Clean Air Act.

If the TSDF air emission standards were not applied to permitted facilities until their permits were renewed (i.e., delay application of new regulations), a substantial portion of the emission and impacts reduction of the standards could be delayed. It is estimated that about 800 of the approximately 5,700 existing facilities would have obtained final permits prior to the promulgation of the rule covering process vents and equipment leaks. It is also estimated that a considerable number of the remaining facilities are likely to be permitted prior to promulgation of today's proposed standards for tanks, surface impoundments, and containers. Once issued, a permit has a term of 5 to 10 years. Therefore, to implement the air emission standards under current regulatory policy may cause a significant delay in achieving the benefits of the air emission standards.

3. Congressional Intent

The air emission standards being proposed today and the air emission standards promulgated for TSDF process vents and equipment leaks are authorized by section 3004(n) of RCRA. This section is part of the Hazardous and Solid Waste Amendments (HSWA) which were signed into law on November 8, 1984. Congress intended for requirements under HSWA to be implemented promptly. This is indicated by the fact that it was specified that requirements contained in the amendments were immediately applicable in all States, whether or not the State was authorized to administer its own hazardous waste program. In addition, Congress established minimum technology requirements in the amendments for major sources of potential environmental releases at facilities. These requirements, such as the requirement that surface impoundments be retrofitted with double liners and leachate collection systems, and the banning of land disposal of certain wastes, were applied independent of the permitting system. These provisions provide further evidence that Congress intended that important HSWA provisions should go into effect immediately.

4. Ease of Implementation

The requirements of the standards proposed today for tanks, surface impoundments, and containers are straightforward; that is, the rule is specific as to who must apply controls and what those controls must be. The same is true for the standards promulgated for process vents and equipment leaks. For both rules, the owner or operator can make a direct measurement or calculation and compare the results against an action level in the standards to determine if controls are required on an emission source. If controls are required, the standards include specifications for equipment applied to suppress emissions (e.g., covers), performance criteria for control devices, and in the case of equipment leaks, the details of the leak detection and repair program that must be implemented. The standards for TSDF air emissions can therefore be described as "self-implementing" in that they can be directly implemented by TSDF without interpretation or intervention by the permitting authority. Also, EPA has previously been successful in applying the controls required by the TSDF air standards to similar emission sources in the chemical and petroleum industries under the Clean Air Act. This experience confirms that air standards of the type being proposed today can be applied directly by facilities without prior permitting review.

In summary, the results of EPA's impact analysis establish TSDF as a major source of organic emissions and health risk. Further, because the standards proposed and promulgated by EPA under RCRA Section 3004(n) are the first major group of standards to address air emissions from TSDF under the HSWA provisions, it would be consistent with Congressional intent to make the rules effective as soon as possible. Finally, because the rules are self implementing, they can be implemented by facilities without prior intervention by the permitting authority. Based on these considerations, EPA has concluded that the substantive control requirements of the air emission standards should apply and be enforced at all TSDF as soon as possible and, consequently, that the standards should

not be implemented under the permit-as-a-shield policy.

One option for expediting implementation of the air emission standards at permitted facilities would be for EPA to exercise its authority to reopen permits specifically to include the requirements of these standards. As noted earlier, however, this would involve a lengthy administrative process and impose a potentially large burden on permitting agencies and the regulated community. (Many permits may have just been issued.) Furthermore, even with a significant commitment to make the necessary permit modifications, this process would likely take years to complete. Thus, the EPA is not proposing to pursue this option.

An alternative option would be to apply the air emission control requirements for interim status facilities directly to permitted facilities. Under this option, facilities with permits as of the effective date of the standards would be required to comply with the air emission standards promulgated for interim status facilities until their permits are renewed, at which time the air standards would be incorporated into the permits. Because it would accomplish the objective of requiring air emission controls at permitted facilities on the effective date of the standards without the administrative burden associated with reopening permits, EPA selected this option for proposal.

The EPA is proposing the following regulatory actions that would make the air emission standards applicable to all facilities (including those that have submitted part A or part B permit applications and those that have received permits) on the effective date:

(1) Standards for tanks, surface impoundments, and containers be added as subpart CC to 40 CFR part 265. These standards would be immediately applicable to interim status facilities upon the effective date (6 months after the promulgation date).

(2) Standards for tanks, surface impoundments, and containers be added as Subpart CC for 40 CFR part 264. Each RCRA permit issued after the effective date must include permit conditions necessary to achieve compliance with these standards.

(3) Section 270.4 of the RCRA permitting regulations be amended to require that facilities that have obtained final permits prior to the effective date (6 months after promulgation) comply with the tank, surface impoundment, and container standards for interim status facilities (i.e., 40 CFR 265 subpart CC) until the facility's permit is reviewed or reissued. Furthermore, this amendment would require the promulgated standards for TSDF process vents (40 CFR 265 subpart AA) and equipment leaks (40 CFR 265 subpart BB) apply to these facilities. This amendment would eliminate the permit-as-a-shield for the air emission standards, but would not require that permits be reopened.

These actions, if adopted, would mean that the air rules promulgated under RCRA section 3004(n) would be applicable to all facilities as of the effective date of the standards finally promulgated. More details on the implementation schedule for the standards proposed today and the standards promulgated for vents and equipment leaks are presented later in this section.

5. Proposed Standards for TSDF Tanks, Surface Impoundments, and Containers

Under the approach discussed above, the standards proposed today for tanks, surface impoundments, and containers would be implemented on the following schedule for existing TSDF's including permitted facilities:

(1) 180 days following promulgation, the standards become effective; all facilities become subject to the new standards;

(2) On the effective date of the standards, each facility that does not have the controls required by the standards in place must have one of the following in the facility's operating record: an implementation schedule indicating when the controls will be installed, or their waste determination that indicates that controls are not required.

(3) No later than 18 months following the effective date (2 years following promulgation), the controls required by the standards must be installed at all facilities where they apply.

All permits issued after the effective date must incorporate the appropriate standards.

Interim status facility owners and operators who have submitted their part B permit applications who have not received their final permit as of the effective date of the standards would be required to modify their part B permit applications to incorporate the requirements of the final rule in 40 CFR parts 264 and 270.

The implementation schedule for permitted and interim status facilities is shown in Figure 1. Interim status facility owners and operators who have submitted part B applications but have not received their final permits as of the effective date of the standards would be required to modify their part B applications to incorporate the part 264 and 270 requirements of the final rule. No specific time period for submittal of the revised part B has been selected yet. However, four possible time period options are being considered by EPA as described below. The EPA requests comments on these options for when part B application information should be submitted.

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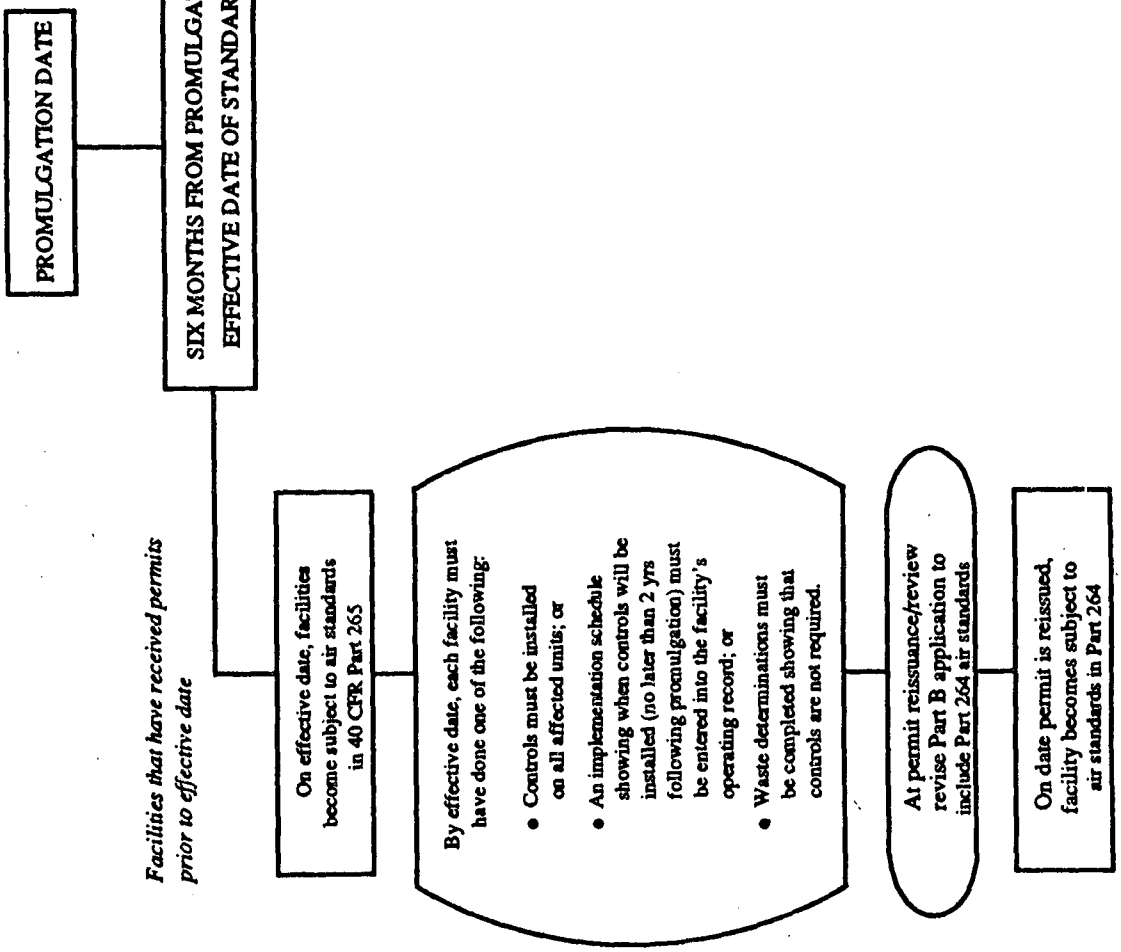
Figure 1. Air Standards for Tanks, Surface Impoundments and Containers: Implementation Schedule for Existing TSDFs With Permits or in Interim Status



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The first option would establish no specific deadline for modification of part B. Under this option, EPA would request the information under § 270.10(e)(4) of the regulations on a case-by-case basis. Once EPA requests it, the owner or operator would then have 6 months to submit the information or the permit could be denied.

The second option would be to establish a nationwide deadline in the rule requiring submittal of a revised part B within 3 months after publication of the notice of final rulemaking. Under this option, owners and operators whose permits were then issued before the effective date of the rule would have unnecessarily submitted their information since their permit would not be required to contain air emission standards (according to the permitting scheme being permitted today).

The third option would require submittal of part B by the effective date of the rule, that is, within 6 months after publication of the notice of final rulemaking. While this option would create some uncertainty for persons who were anticipating permit issuance in the period before the effective date as to whether they had to submit their part B, it would allow for prompt issuance of permits after the effective date. Historically, facility owners and operators are allowed up to 6 months to develop part B information when a facility or unit becomes subject to new requirements.

The fourth option would establish a national deadline 3 months after the effective date for submittal of part B. Although this option would eliminate the uncertainty inherent in the second and third options as to which permits will need to contain permit conditions for the air emission standards, it could delay by 3 months permit issuance in some cases.

Newly constructed TSDF are required to submit part A and part B permit applications, and to receive a final permit prior to construction as required by § 270.10. Following the effective date of the standards proposed today, a part B application for a new facility must be in compliance with the standards as contained in 40 CFR part 264, if applicable. Therefore, all controls required by the standards would have to be in place and operating upon startup.

Similarly, new waste management units added to existing facilities would have to be equipped with the required controls prior to startup. For a new unit added to an existing permitted facility, a permit modification would be necessary. Where a new unit is added to a facility in interim status, the owner or operator must submit a revised part A application (§ 270.72(c)) including an explanation of the need for the new unit, and then receive approval from the permitting authority.

The EPA considered allowing up to 18 months past the effective date of the standards for new facilities to complete the installation of air emission controls (as is allowed in the proposal for existing facilities). This was rejected, however, for two reasons. First, with today's proposal, owners or operators considering the construction of new facilities are put on notice that controls for air emissions will be required in the future, and therefore have ample time to include air emission controls in the design of new facilities. Secondly, with the opportunity to include air emission controls in the design of new facilities, design and construction should be easier than for existing facilities that have to be retrofitted with controls.

An existing solid waste management unit (or facility) may become a hazardous waste management unit (or facility) requiring a RCRA permit when a waste becomes newly listed or identified as hazardous. Owners and operators of facilities not previously requiring a RCRA permit who have existing units handling newly listed or identified hazardous waste can submit a part A application and gain interim status. Under the proposed implementation approach, the air emission standards proposed today would be implemented at these facilities on the following schedule:

(1) 180 days following the date the managed waste is listed or identified as hazardous, the standards become effective; facilities become subject to the standards.

(2) On the effective date of the standards, each facility that does not have the controls required by the standards in place must have one of the following in the facility's operating record: (1) an implementation schedule indicating when the controls will be installed, or (2) their waste determination that indicates that controls are not required.

(3) No later than 18 months following the effective date the controls required by the standards must be installed at all facilities.

6. Omnibus Permitting Authority

The permitting authority cited by section 3005 of RCRA and codified in § 270.32 states that permits issued under this section ". . . shall contain such terms and conditions as the Administrator or State Director determines necessary to protect human health and the environment." This section, in effect, allows permit writers to require, on a case-by-case basis, emission controls that are more stringent than those specified by a standard. This omnibus authority could be used in situations where, in the permit writer's judgment, there is an unacceptably high residual risk after application of controls required by an air emission standard.

As previously stated in Section II, the approach that EPA is using for today's proposed regulatory action is based on first controlling TSDF organic emissions as a class and to follow this, if necessary, with another phase of regulations to further reduce the risk from air emissions. During the interim, permit writers could use their omnibus permitting authority to require air emission controls similar to those proposed today or more stringent controls at TSDF where a high residual risk remains after implementation of today's proposed air emission standards.

The EPA is currently preparing a guidance document to be used by permit writers to help identify facilities that would potentially have high residual risk. The guidance document will include step by step procedures to be used to identify potentially high risk facilities and will include detailed guidance for making a formal, site-specific risk assessment. Methods for providing additional emissions control at facilities identified as having high residual risk after implementation of the standards for organic air emissions would also be included and will cover both work practice controls and technological controls. Detailed examples of both risk assessments and the provision of additional emissions control will be included in the guidance. Checklists will be included to assist permit writers to assure that all appropriate actions are taken.

7. Final Standards for TSDF Process Vents and Equipment Leaks

The only impact of today's proposal to eliminate the permit-as-a-shield as applied to the promulgated standards for vents and equipment leaks is on facilities that will have obtained permits by the effective date of these standards. Under the § 270.4 requirements, these facilities would not be subject to the standards until their permits were modified or reissued. Under today's proposal, the implementation schedule for these facilities would be as follows:

(1) 180 days following promulgation of the standards proposed today, these facilities become subject to the standards for vents and equipment leaks; compliance with the standards for

equipment leaks is required by this date. Each facility that does not have control devices required by the standards in place must have an implementation schedule in the facility's operating record indicating when the controls will be installed.

(2) No later than 18 months following the effective date of the standards proposed today (2 years following promulgation), any control devices required by the standards for vents and equipment leaks must be installed at these facilities.

The implementation schedule for the TSDF process vent and equipment leak standards at these facilities is shown in Figure 2.

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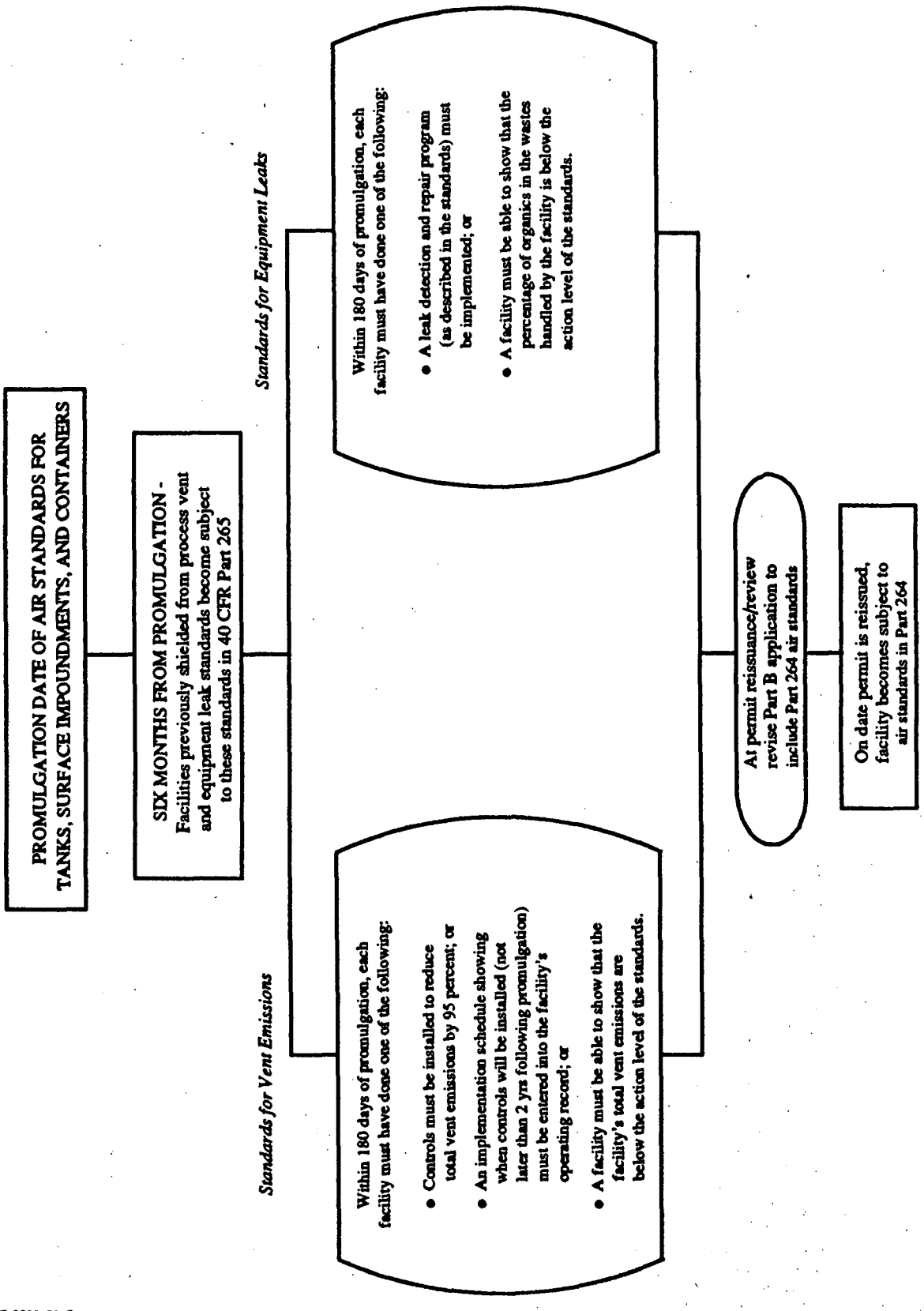
Figure 2. Air Standards for Process Vents and Equipment Leaks: Implementation Schedule for Existing Facilities with Permits as of (date)



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B. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State (see 40 CFR part 271 for the standards and requirements for authorization). Following authorization, EPA retains enforcement authority under sections 3008, 7003, and 3013 of RCRA, as well as inspection authority under Section 3007, although authorized States have primary enforcement responsibility.

Prior to the HSWA, a State with final authority administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for facilities in that State. When new, more stringent Federal requirements were promulgated or enacted, the State was obligated to enact equivalent requirements within specified time frames. New Federal requirements did not take effect as Federal law in an authorized State until the State adopted the requirements as State law and was authorized for the requirements.

In contrast, under section 3006(g)(1) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time they take effect in nonauthorized States. The EPA is directed to carry out those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authority to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA requirements apply in authorized States in the interim.

Today's rule is proposed pursuant to section 3004(n) of RCRA, a provision added by HSWA. Therefore, the Agency is proposing to add the requirements to Table 1 in § 271.1(j), which identifies the Federal program requirements that are promulgated pursuant to the HSWA and that take effect in all States, regardless of their authorization status. In particular, EPA is considering including the portion of today's proposal related to 90-day tanks and containers as part of the HSWA rules. The HSWA added section 3004(n), which provides that EPA must "promulgate such regulations for monitoring and control of air emissions at hazardous waste treatment, storage, and disposal facilities, . . . as may be necessary to protect human health and the environment." Based on EPA's analysis of the possibility for release of organics before waste reaches a TSDF, EPA believes that controls on tanks and containers at generator facilities should be considered as necessary regulations for effective control of air emissions at TSDF. Therefore, EPA seeks comment on the concept of including the controls at generator sites in the provisions that EPA will implement directly in authorized States. The EPA may select this approach in the final rule.

C. Effect on State Authorizations

The EPA will implement today's rule when finalized in authorized States until either: (1) They modify their programs to adopt these rules and receive final authorization for the modification, or (2) they receive interim authorization as described below. Because the standards are proposed pursuant to the HSWA, a State submitting a program modification may apply to receive either interim or final authorization under section 3006(g)(2) or 3006(b), respectively, on the basis of requirements that are substantially equivalent or equivalent to EPA's. The procedures and schedule for State program modifications for either interim or final authorization are described in 40 CFR 271.21. It should be noted that all HSWA interim authorizations will expire automatically on January 1, 1993 (see 40 CFR 271.24(c)). The EPA invites comment on whether EPA should, in the final rule, modify § 271.24(c) to extend this deadline.

Specifications in 40 CFR 271.21(e)(2) require that States having final authorization must modify their programs to reflect Federal program changes, and subsequently must submit the modifications to EPA for approval. The deadline by which States must modify their programs to adopt this proposed regulation will be determined by the date of promulgation of the final rule, in accordance with 40 CFR 271.21(e)(2). This deadline can be extended in certain cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the State requirements become subtitle C RCRA requirements.

A State that submits its official application for final authorization less than 12 months after the effective date of these standards is not required to include standards equivalent to these standards in its application. However, the State must modify its program by the deadlines set forth in 40 CFR 271.21(e). States that submit official applications for final authorization 12 months after the effective date of these standards must include standards equivalent to these standards in their applications. The 40 CFR 271.3 sets forth the requirements a State must meet when submitting its final authorization application.

States with authorized RCRA programs may already have requirements similar to those in today's proposed rule. Such State regulations have not been assessed against the Federal regulations being proposed today to determine whether they meet the tests for authorization. Thus, a State is not authorized to implement these requirements as RCRA requirements until the State program modification is assessed against Federal requirements and approved. Of course, States with existing standards may continue to administer and enforce their standards as a matter of State law. In implementing the Federal program, EPA will work with States under cooperative agreements to minimize duplication of efforts. In many cases, EPA will be able to defer to the States in their efforts to implement their programs, rather than take separate actions under Federal authority.

XI. Administrative Requirements

A. Public Hearing

If requested, EPA will hold a public hearing on August 20, 1991 (Julia Stevens, FTS 629–5578). The hearing will be held at EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina, beginning at 10:00 a.m. Anyone wishing to make a statement at the hearing should notify Julia Stevens, Standards Development Branch (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, NC, 27711, telephone (919) 541–5578, by August 9, 1991.

Oral and written statements may be submitted at the public hearing. Persons who wish to make oral presentations must restrict them to 15 minutes and are encouraged to have written copies of their complete comments for inclusion in the public record.

B. Docket

The docket for this rulemaking is available for public inspection at the RCRA Docket Office (OS–305) in room 2427 of the U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket room is open from 9 a.m. to 4 p.m., Monday through Friday, except for Federal holidays. The public must make an appointment to review docket materials and should call the docket at (202) 475–9327 for appointments. The public may copy a maximum of 100 pages of material from any one regulatory docket at no cost. Additional copies cost $0.15/page. The docket number is F–91–CESP–

FFFFF. The docket contains a copy of all references cited in the Background Information Document for the proposed rules, as well as other relevant reports and correspondence. A docket index is available for review at the docket office.

C. External Participation

Development of the basic background information for these proposed standards included consultation with appropriate advisory committees, independent experts, and Federal departments and agencies. The EPA will welcome comments on all aspects of the proposed regulation, including economic and technological issues.

D. Office of Management and Budget Reviews

1. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request document has been prepared by EPA (ICR No. 1593.01), and a copy may be obtained from Ms. Sandy Farmer, Information Policy Branch (PM-223), U.S. EPA, 401 M Street, SW., Washington, DC 20460 or by calling (202) 382-2740.

Public reporting burden for this collection of information is estimated to average 56 hours per respondent per year, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

2. Executive Order 12291 Review

Executive Order No. 12291 requires each Federal agency to determine if a regulation is a "major" rule as defined by the order and "to the extent permitted by law," to prepare and conside a Regulatory Impact Analysis (RIA) in connection with every major rule. Major rules are defined as those likely to result in:

1. An annual cost to the economy of $100 million or more; or
2. A major increase in costs or prices for consumers or individual industries; or
3. Significant adverse effects on competition, employment, investment, productivity, innovation, or international trade.

The EPA has judged the proposed Hazardous Wastes TSDF air emission standards for organics control to be a major rule based on estimated national control costs (i.e., annualized costs in excess of $100 million). The EPA has prepared a draft RIA that includes estimates of costs, benefits, and net benefits associated with five alternative control options. The draft analysis, titled Hazardous Waste TSDF—Regulatory Impact Analysis for Proposed RCRA Air Emission Standards, is available in the docket.

The RIA results indicate that all control options examined would increase the unit cost of hazardous waste management services by less than 1 percent. The results also indicate a decrease in the number of jobs at TSDF but the decrease is so small that employment dislocations would probably be few, if any. Efforts undertaken by waste generators to minimize the quantity of hazardous waste in response to the waste management service price increase, could, in the aggregate, imply facility closures; however, it appears likely that the reductions will be distributed across all facilities and that the number of closures, if any, will be nominal.

Unit cost increases for storage-only facilities are substantial for several industry sectors and options when viewed as a share of hazardous waste management costs. However, storage facility closures also appear unlikely.

At generator sites that operate 90-day tanks and containers, the economic analysis indicated that the prices of goods and services could rise slightly because of the costs to the generators to comply with the proposed standards. The impact of the proposed standards on the volume of wastes stored and the number of jobs are estimated to be negligible, and employment dislocations and plant closures are unlikely.

The draft RIA has been submitted to OMB for review under Executive Order 12291. Written comments from OMB and any written EPA response to these comments are available for public inspection at the docket office cited above. A final RIA will be issued at the time of promulgation of the final rulemaking.

3. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, whenever an Agency publishes any proposed or final rule in the **Federal Register**, it must prepare a Regulatory Flexibility Analysis (RFA) that describes the impact of the rule on small entities (i.e., small businesses, organizations, and governmental jurisdictions). That analysis is not necessary, however, if an agency's administrator certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The EPA has established guidelines for determining whether an RFA is required to accompany a rulemaking package. The guidelines state the criteria for determining when the number of affected small entities is "substantial" (i.e., at least 20 percent of the small entities) and when an impact is "significant." The determination of significance essentially depends upon compliance costs, production costs, and predicted closures. The draft RIA, cited in the preceding paragraph, describes the criteria in detail and the economic impact model employed to estimate the effects of a regulation on small entities (refer to Chapter 6 of the RIA for additional details).

The results of the economic impact model in the RIA indicate that the effects of regulation on small entities are minimal. The number of affected small entities is insubstantial, and the impacts are insignificant.

Accordingly, I hereby certify that the regulation will not have a significant impact on a substantial number of small entities. Therefore, this regulation does not require an RFA.

List of Subjects in 40 CFR Parts 60, 260, 264, 265, 270, and 271

40 CFR Part 60

Air pollution control, Test method, Vapor-phase organic concentration, Volatile organic concentration, Waste, Waste testing.

40 CFR Part 260

Definitions, Hazardous waste.

40 CFR Parts 264 and 265

Air pollution control, Container, Control device, Hazardous waste, Hazardous waste management unit, Inspection, Miscellaneous unit, Monitoring, Recordkeeping, Reporting, Standards, Surface impoundment, Tank, TSDF, Waste determination.

40 CFR Part 270

Administrative practice and procedure, Air pollution control, Confidential business information, Hazardous waste, Permit, Permit modification, Reporting and recordkeeping requirements.

40 CFR Part 271

Administrative practice and procedure, Air pollution control, Confidential business information, Hazardous waste, Reporting and recordkeeping requirements.

Dated: July 1, 1991.

William K. Reilly,

Administrator.

Appendix 1. Waste Determination Statistical Procedures

Today's proposed standards would require waste determinations be performed if an owner or operator chooses to place waste with a volatile organic concentration less than 500 ppmw in a tank, surface impoundment, or container not equipped with the specified organic emission controls. The first section of this appendix describes the statistical procedure that is proposed today as 40 CFR 264 appendix X and 40 CFR 265 appendix VI to compute the waste volatile organic concentration value for comparison to the 500 ppmw limit.

Under the proposed standards, the waste determination would need to be performed initially by the effective date of the standards and repeated at least annually and, additionally, every time there is a change in the waste being managed or in the operation that generates or treats the waste that may affect the regulatory status of the waste. Section VII of this preamble discusses the alternatives considered by EPA for the selection of the interval for periodic waste determinations. As an alternative to the annual frequency waste determination requirement included in the proposed standards, EPA considered requiring a monthly frequency with a less frequent interval being allowed for certain waste conditions. The second section of this appendix describes the statistical procedure EPA developed to establish for which wastes the less frequent interval could be used based on the variability of monthly waste determination results for a 6-month period.

A. Statistical Procedure To Determine if Waste Volatile Organic Concentration is Less Than 500 ppmw

The direct measurement waste determination as described in section VII of this preamble would require that at least four waste samples be collected and analyzed for volatile organic concentration. The samples would need to be collected as close together in time as is practical, so that any variation in results can be attributed to sampling and analytical variability rather than process variability. The samples would be analyzed using Reference Method 25D/Test Method 5100 as described in section XI of this preamble. To compare these multiple test results to the 500 ppmw limit, a single concentration value from the four or more measured concentration values must be obtained. A statistical t-test would be used to obtain a single concentration value.

The statistical t-test involves adding the average of the logarithms of the measured volatile organic concentrations to an estimate of the measurement standard error (sampling and analytical error), and then comparing the appropriate value (exponential of the sum) to 500 ppmw. The t-test relies on the assumption that the quantities being compared are normally distributed. Since the logarithms of concentrations are approximately normally distributed, they are used in lieu of the concentration values directly obtained from Reference Method 25D or Test Method 5100. To perform the statistical t-test, some measure of variability among sample results taken at a given point in time is needed. This measurement variability (or standard deviation) can be estimated directly if multiple samples are taken at each of two or more points in time, and then the standard deviations estimated from each of those times are pooled.

To pool the results from multiple sampling periods, it is necessary to know or assume how the standard deviation of the measurements changes when the waste concentration increases or decreases. If the standard deviation is a constant at all measured concentration values, then the pooling of results from different time periods can be done directly using the measured concentration values. If the standard deviation varies in proportion to the magnitude of the measurements, then the natural logarithms of the measured values should be used when calculating the mean and standard deviation. It is EPA's judgment that standard deviations of waste test results will tend to be proportional to the waste concentration. For example, in absolute units (ppmw), EPA believes that a process that yields a waste having a volatile organic concentration of about 400 ppmw would tend to have a larger sampling and analytical variability (say, a standard deviation of 40 ppmw) than would a process that yields a waste having a volatile organic concentration of about 100 ppmw (say, a standard deviation of 10 ppmw). In other words, if the process level changed, then the standard deviation would tend to change in a proportionate fashion. Under the conditions of this example, the (natural) logarithms of the concentration measurements are more appropriate than the concentration measurements themselves for use in pooling measurement results from several sampling times. Therefore, EPA chose to use the natural logarithms of the measured values for these statistical calculations.

At any time, i, the mean of the logarithms of the measured values of volatile organic concentration, $\bar{X}_i$, is obtained by averaging the logarithms of the measured values:

$$\bar{X}_i = \sum_j X_{ij}/n_i \qquad \text{(Eq. 1)}$$

Where:

n_i = the number of waste samples at time i.

X_{ij} = the natural logarithm (ln) of the volatile organic concentration of sample j taken at time i.

The standard deviation, S_i, is obtained as follows:

$$S_i = \sqrt{\sum_{k=0}^{i} (n_k - 1) s_k^2 / K_i}$$

(Eq. 2)

Where:

$$K_i = \sum_{k=0}^{i} (n_k - 1)$$

(Eq. 3)

$$s_k = \sqrt{\frac{\sum_j X_{kj}^2 - (\sum_j X_{kj})^2 / n_k}{n_k - 1}}$$

(Eq. 4)

X_{kj} = Natural logarithm (ln) of the measured volatile organic concentration of sample j taken at time k.

n_k = number of waste samples selected at time k.

For the initial determination (i=0 and k=0), the standard deviation, S_0, is equal to s_0. If an owner or operator conducts the minimum amount of testing during subsequent sampling periods, which consists of collecting and analyzing a single sample each month (or a single sample each 6 months if a reduced sampling frequency is being used), then the standard deviation calculated for the initial set of sampling results, S_0, is assumed to apply to the results of each subsequent determination and is used in making comparisons of the logarithms of measured values with the 500 ppmw limit.

To determine if the volatile organic concentration of a waste is below 500 ppmw, the mean of the logarithms of the measurements at time i, X_i, would be added to the product of the standard deviation, S_i, and a multiplier; the exponential of this sum would then be compared with 500 ppmw to determine if the waste can be managed in units that are not controlled for air emissions. The value of the multiplier depends on the number of samples taken and can be obtained from Column 2 in Table 2 by selecting the value corresponding to the value of K_i in Column 1. The following condition must be true in order for the waste to qualify for management in units that are not controlled for organic emissions:

$\exp(\bar{X}_i+(t_i\times S_i)/\sqrt{n_i})<500$ (or an alternate level for treated waste) (Eq. 5)

Where:

X_i=The mean of the natural logarithms of the measured values obtained from samples at the current time, i, as defined by Eq. 1.

t_i=A value obtained from Column 2 of Table 2 corresponding to the value of K_i in Column 1.

S_i=The standard deviation as defined by Eq. 2.

n_i=The number of samples collected at the current time, i.

TABLE 2.—MULTIPLIERS FOR USE IN t-TEST

K_i (from Eq. 3)	Multiplier (t_i) (for Eq. 5)	Multiier (t'_i) (for Eq. 6)
1	3.078	6.314
2	1.886	2.920
3	1.638	2.353
4	1.533	2.132
5	1.476	2.015
6	1.440	1.943
7	1.415	1.895
8	1.397	1.860
9	1.383	1.833
10	1.372	1.812
11	1.363	1.796
12	1.356	1.782
13	1.350	1.771
14	1.345	1.761
15	1.341	1.753
16	1.337	1.746
17	1.333	1.740
18	1.330	1.734
19	1.328	1.729
20	1.325	1.725
21	1.323	1.721
22	1.321	1.717
23	1.319	1.714
24	1.318	1.711
25	1.316	1.708
26	1.315	1.706
27	1.314	1.703
28	1.313	1.701

In some situations, an owner or operator may benefit from taking multiple samples during one or more of the sampling periods following the initial determination. For example, if the estimate of the standard deviation calculated for the initial set of sample results is large and the mean value of the initial test or a value measured during a follow-up test is near the 500 ppmw limit, a reduction in the standard deviation or the multiplier may be needed in order for the measured values to meet the conditions of the t-test. Multiple sampling at any sampling time will always reduce the value of the multiplier, and may reduce the value of the estimated standard deviation as well.

B. Statistical Procedure To Determine Waste Determination Interval

The statistical procedure developed by EPA for determining the waste conditions for which the less frequent waste determination interval would be appropriate is also based on using a statistical t-test. In deriving the multipliers for the statistical t-test described in the first section of this appendix, the objective set by EPA was to ensure that the chance of a waste sample being incorrectly determined to be below 500 ppmw would be no more than 1 in 10. The EPA concluded that if a waste consistently meets the condition of Eq. 5 for some minimum time period, and if the waste could meet a more stringent t-test where the chance of an incorrect determination is less than 1 in 10, thus providing increased assurance that no incorrect determinations would be made, then a reduced sampling frequency would be appropriate. After examining several options, EPA concluded that a time period of 6 months would provide sufficient evidence that a waste will consistently meet the condition of Eq. 5 and further concluded that a more stringent test where the chance of an incorrect determination is no more than 1 in 20 would provide adequate assurance that a reduced sampling frequency could be employed. Whereas the test associated with Eq. 5 is based on the mean of all observations taken at time i, the test for assessing sampling frequency considers all individual observations taken at time i plus all observations from the five most recent sampling periods.

In the procedure derived to test for the appropriateness of a reduced sampling frequency, an owner or operator would be allowed to reduce his sampling frequency from one or more samples per month to one or more samples at a less frequent interval (e.g., semiannually, annually) provided that every sample taken over the previous six sampling periods meets the following condition:

$\exp(X_{kj}+(t'_i\times S_i))<500$ (or an alternate level for treated waste) (Eq. 6)

Where:

X_{kj}=The logarithm of the measurement of sample j taken at time k, where k=i, i−1, i−2, i−3, i−4, and i−5.

t'_i=A value taken from Column 3 of Table 2 corresponding to a Column 1 value equal to K_i.

S_i=The standard deviation as previously defined (Eq. 2).

If the condition in Eq. 6 is true for each test result for the previous six sampling periods, the owner or operator would be allowed to switch from monthly to less frequent testing and would be allowed to continue to use the reduced frequency as long as the condition in Eq. 6 is met. If at any time the condition in Eq. 6 is not met, then the owner or operator would be required to switch back to or continue using monthly testing. At any time that the condition of Eq. 6 is not met, an owner or operator would have the option of collecting and analyzing more than the minimum number of samples to potentially reduce the estimated variability of the samples and thus show that the conditions are met.

Note that the condition in Eq. 6 differs from the condition in Eq. 5 in that it uses a larger multiplier (i.e., for each row of Table 2, the Column 3 value is larger than the Column 2 value) and it does not contain the quantity n_i. As a result of these differences, the t-test for switching from monthly to less frequent testing is more stringent than the t-test for determining if the volatile organic concentration is below the 500 ppmw limit.

Because of the complexity of the statistical procedure presented here, EPA developed an example form, shown in Figure 3, that simplifies the calculation procedure to determine

whether or not a reduced sampling frequency can be used.

Figure 3.—Waste Analysis Form—Sample Worksheet

A. Sample Period (sample collection date)
B. Measured concentration value for each sample collected during period (minimum of four samples)
C. Logarithms of values in Row B
D. Number of values in Row C
E. Average of values in Row C
F. Variance of values in Row C
G. [Row D]−1
H. [Row D prior period]+[Row G]
I. [Row D prior period]×[Row L prior period]
J. [Row F]×[Row G]
K. [Row I]+[Row J]
L. [Row K]/[Row H]
M. [Row L]$^{0.5}$
N. Multiplier (Table 2, column 2; K_1=Row H)
O. [Row M]×[Row N]/[Row D]$^{0.5}$
P. [Row E]+[Row O]
Q. exp [Row P]
R. Is Row Q<500?
If "yes" ► go to Row S; If "no" ► stop
S. Is Row Q<500 for last 6 periods?
If "yes" ► go to Row T; If "no" ► stop
T. Multiplier (Table 2, column 3; K_1=Row H)
U. exp [[Row M]×[Row T]]
V. 500/[Row U]
W. Is Row V>all Row B for last 6 periods?
If "yes" ► semi-annual sampling allowed
If "no" ► monthly sampling required

The form includes instructions to determine if the conditions of Eq. 5 and Eq. 6 are met. On the form, Row B pertains to measured concentration values from the waste sample analyses, Row C pertains to the logarithms of the measured concentration values, Rows D through M involve some preliminary calculations, Rows N through S constitute the test to determine if the volatile organic concentration of the sampled waste is below 500 ppmw, and Rows T through W contain the test for determining if a reduced sampling frequency can be used.

For the reasons set out in the preamble, title 40, chapter I, parts 60, 260, 264, 265, 270, and 271 of the Code of Federal Regulations are proposed to be amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

1. The authority citation for part 60 continues to read as follows:

Authority: Sections 111, 301(a) of the Clean Air Act as amended (42 U.S.C. 7411, 7601(a)), unless otherwise noted.

2. Appendix A is amended by adding test methods 25D and 25E:

METHOD 25D—Determination of the Volatile Organic Concentration of Waste Samples

Introduction

Performance of this method should not be attempted by persons unfamiliar with the operation of a flame ionization detector (FID) or an electrolytic conductivity detector (ELCD) because knowledge beyond the scope of this presentation is required.

1. Applicability and Principle

1.1 Applicability. This method is applicable to the determination of the volatile organic concentration of wastes.

1.2 Principle. A sample of waste is collected from a source as close to the point of generation as practical. The sample is then purged with nitrogen to separate certain organic compounds. Part of the sample is analyzed for carbon concentration, as methane, with an FID, and part of the sample is analyzed for chlorine concentration, as chloride, with an ELCD. The volatile organic concentration is the sum of the carbon and chlorine content of the sample.

2. Apparatus

2.1 Sampling. The following equipment is required:

2.1.1 Static Mixer. Installed in-line or as a by-pass loop, sized so that the drop size of the dispersed phase is no greater than 1000 μm. If the Installation of the mixer is in a by-pass loop, then the entire waste stream shall be diverted through the mixer.

2.1.2 Tap. Installed no further than two pipe diameters downstream of the static mixer outlet.

2.1.3 Sampling Tube. Flexible Teflon, 0.25 in. ID. **Note:** Mention of names or specific products does not constitute endorsement by the Environmental Protection Agency.

2.1.4 Sample Container. Borosilicate glass or polytetrafluoroethylene (PTFE), 15 to 50 ml, and a Teflon lined screw cap capable of forming an air-tight seal.

2.1.5 Cooling Coil. Fabricated from 0.25 in. ID 304 stainless steel tubing with a thermocouple at the coil outlet.

2.2 Analysis. The following equipment is required:

2.2.1 Purging Apparatus. For separating the organic compounds from the waste sample. A schematic of the system is shown in Figure 1. The purging apparatus consists of the following major components.

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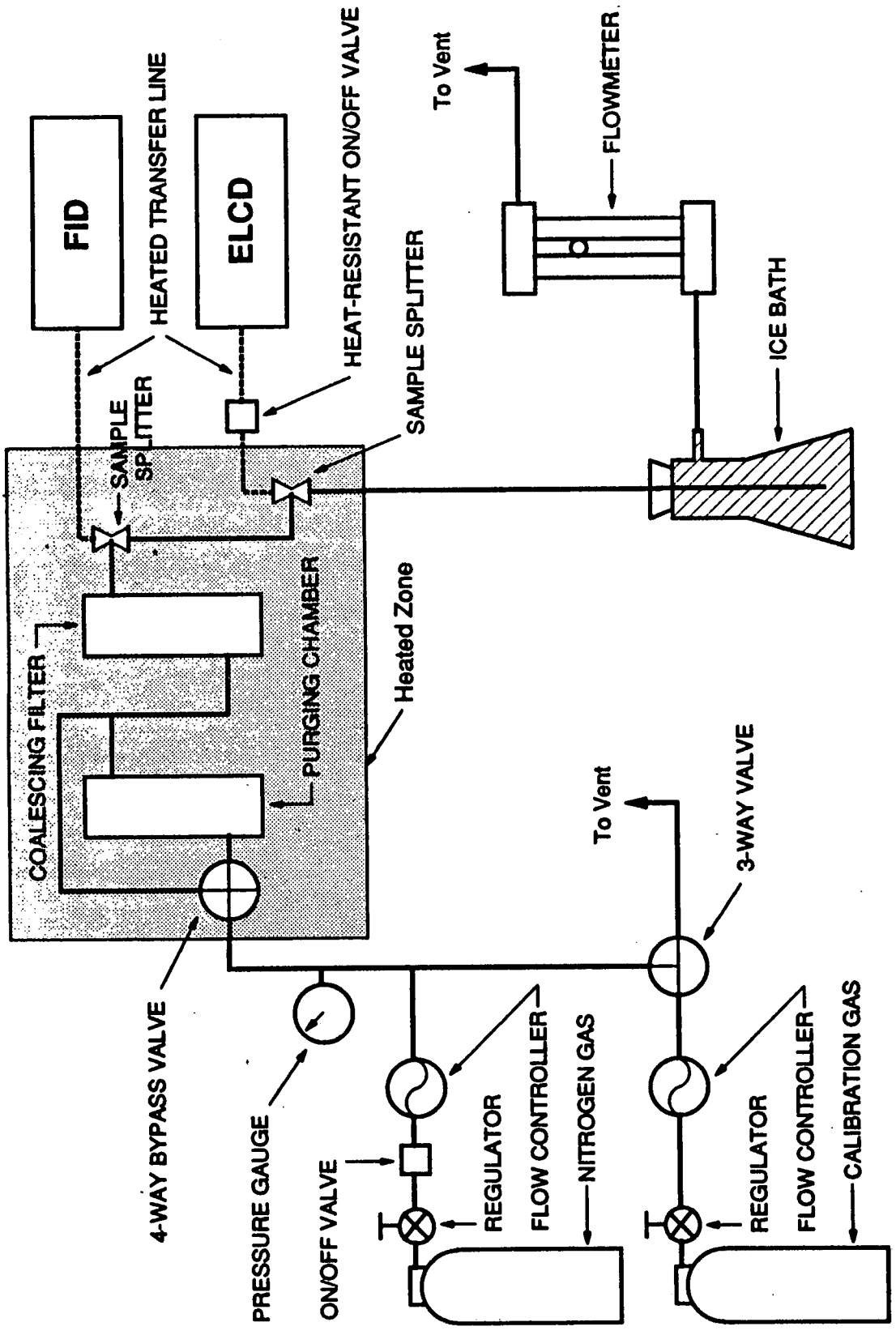

Figure 1. Schematic of Analytical System

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2.2.1.1 Purging Chamber. A glass container to hold the sample while it is heated and purged with dry nitrogen. The cap of the purging chamber is equipped with three fittings: one for a purging lance (fitting with the #7 Ace-thread), one for the Teflon exit tubing (side fitting, also a #7 Ace-thread), and a third (a 50-mm Ace-thread) to attach the base of the purging chamber as shown in Figure 2. The base of the purging chamber is a 50-mm inside diameter (ID) cylindrical glass tube. One end of the tube is open while the other end is sealed. Exact dimensions are shown in Figure 2.

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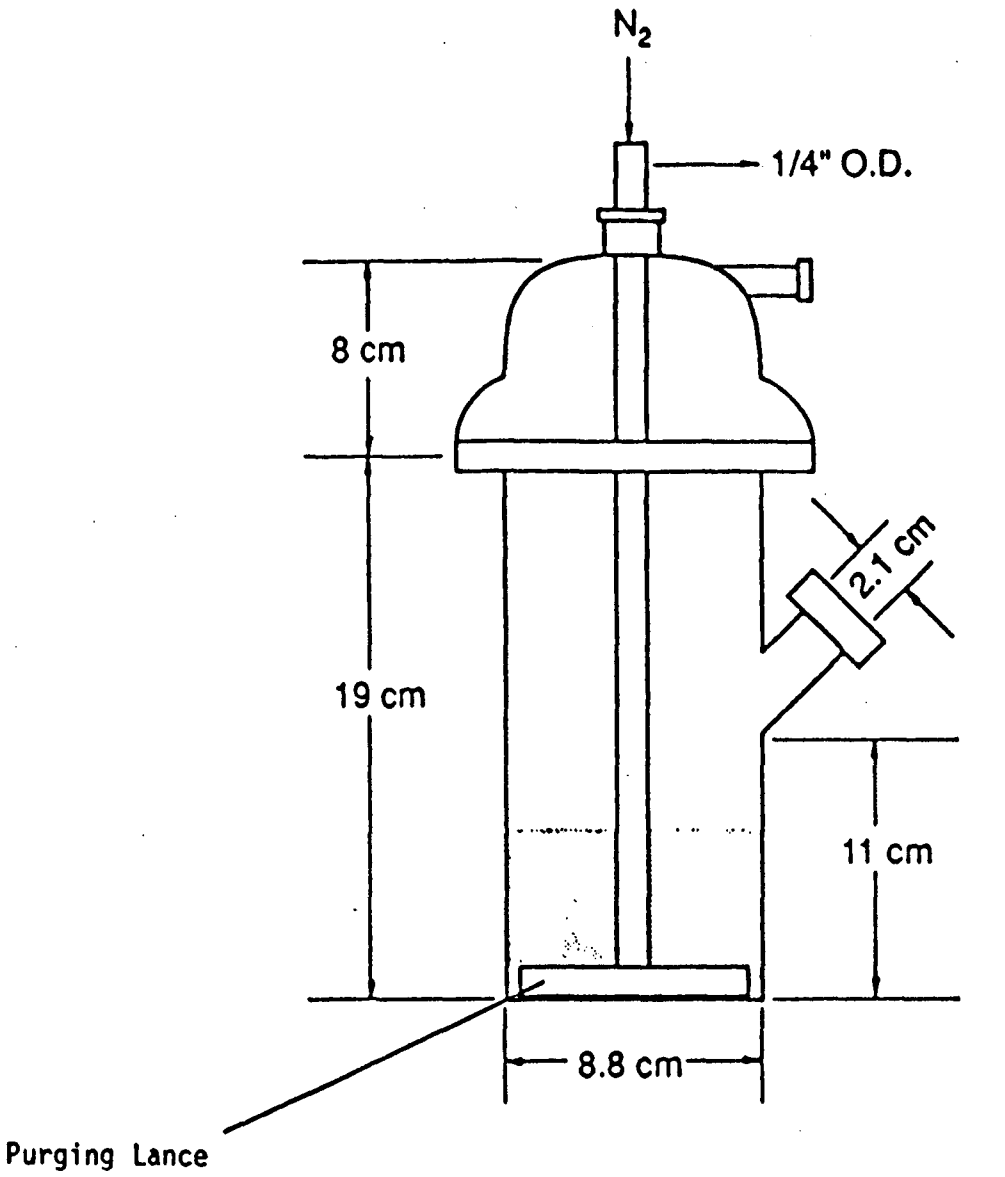

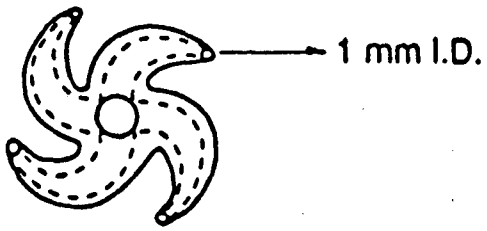

End View of FDD

Figure 2. Schematic of Purging Chamber.

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2.2.1.2 Purging Lance. Glass tube, 6-mm OD by 30 cm long. The purging end of the tube is fitted with a four arm bubbler with each tip drawn to an opening 1 mm in diameter. Details and exact dimensions are shown in Figure 2.

2.2.1.3 Coalescing Filter. Porous fritted disc incorporated into a container with the same dimensions as the purging chamber. The details of the design are shown in Figure 3.

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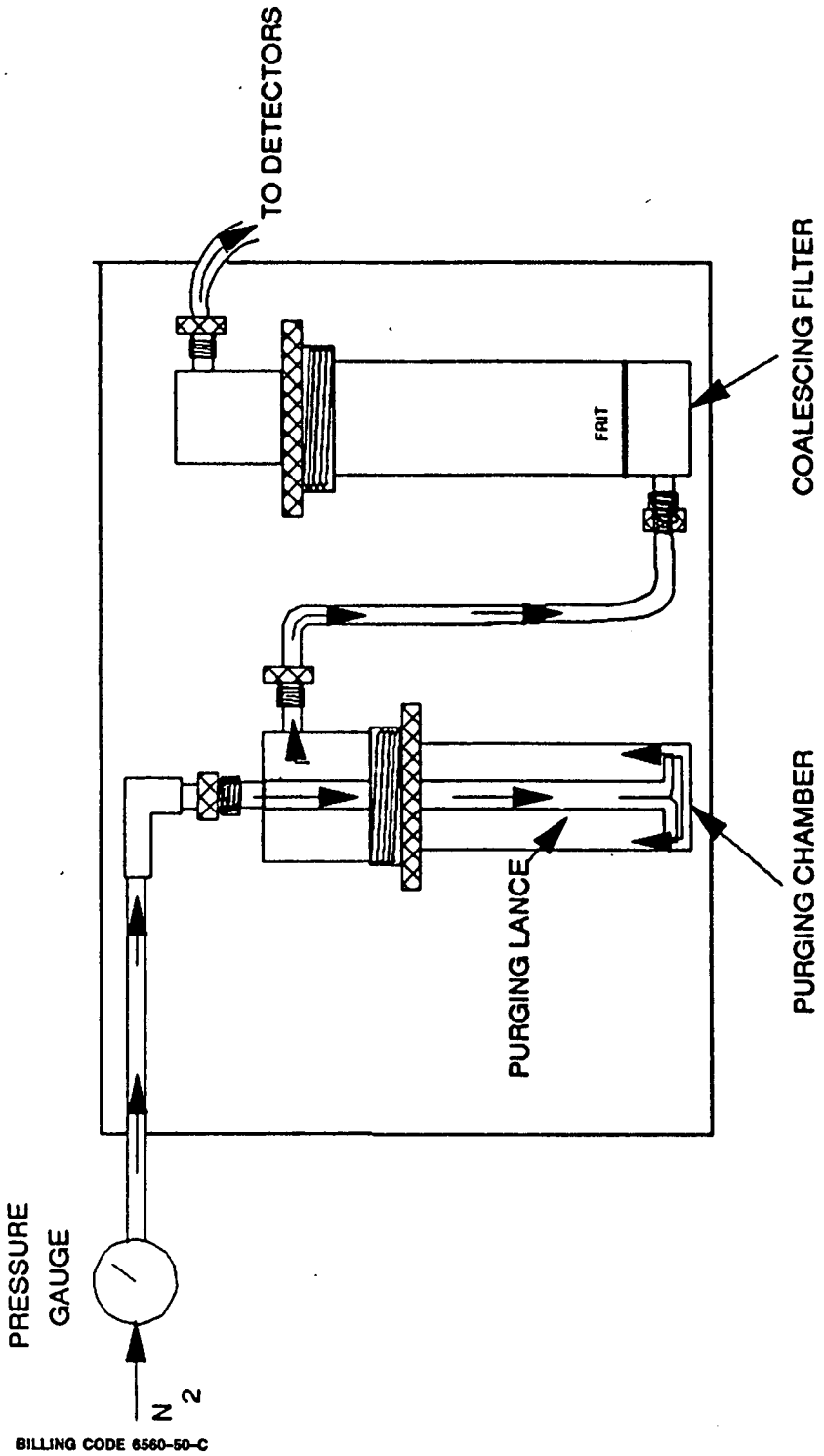

Figure 3. Orientation of Purging Chamber and Coalescing Filter.

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2.2.1.4 Constant Temperature Chamber. An oven capable of maintaining a temperature around the purging chamber and coalescing filter of 75±5 °C.

2.2.1.5 Three-way valve. Manually operated, stainless steel. To introduce calibration gas into system.

2.2.1.6 Flow Controllers. Two adjustable. One capable of maintaining a purge gas flow rate of 6+.06 l/min. The other capable of maintaining a calibration gas flow rate of 1–100 ml/min.

2.2.1.7 Rotameter. For monitoring the air flow through the purging system (0–10 l/min).

2.2.1.8 Sample Splitters. Two heated flow restrictors. At a purge rate of up to 6 l/min, one will supply a constant flow to the ELCD. The second will split the analytical flow between the FID and the vent. The approximate flow to the FID will be 40 ml/min and to the ELCD will be 15 ml/min, but the exact flow shall be adjusted to be compatible with the individual detector and to meet its linearity requirement.

2.2.1.9 Filter Flask. With one-hole stopper. Used to hold ice bath. Excess purge gas is vented through the flask to prevent condensation in the flowmeter and to trap volatile organic compounds.

2.2.1.10 Four-way Valve. Manually operated, stainless steel. Placed inside oven, used to bypass purging chamber.

2.2.1.11 On/Off Valves. Two, stainless steel. One heat resistant up to 130 °C and placed between oven and ELCD. The other a toggle valve used to control purge gas flow.

2.2.1.12 Pressure Gauge. Range 0–40 psi. To monitor pressure in purging chamber and coalescing filter.

2.2.2 Volatile Organic Measurement System. Consisting of an FID to measure the carbon concentration, as methane, of the sample and an ELCD to measure the chlorine concentration.

2.2.2.1 FID. An FID meeting the following specifications is required:

2.2.2.1.1 Linearity. A linear response (±5 percent) over the operating range as demonstrated by the procedures established in Section 5.1.1.

2.2.2.1.2 Range. A full scale range of 50 pg carbon/sec to 50 μg carbon/sec. Signal attenuators shall be available to produce a minimum signal response of 10 percent of full scale.

2.2.2.1.3 Data Recording System. Analog strip chart recorder or digital integration system compatible with the FID for permanently recording the output of the detector. The recorder must have the capability to start and stop integration at points selected by the operator.

2.2.2.2 ELCD. An ELCD meeting the following specifications is required. **Note:** A ¼-in. ID quartz reactor tube is recommended to reduce carbon buildup and the resulting detector maintenance.

2.2.2.2.1 Linearity. A linear response (±10 percent) over the response range as demonstrated by the procedures in Section 5.1.2.

2.2.2.2.2 Range. A full scale range of 5.0 pg/sec to 500 ng/sec chloride. Signal attenuators shall be available to produce a minimum signal response of 10 percent of full scale.

2.2.2.2.3 Data Recording System. Analog strip chart recorder or digital integration system compatible with the output voltage range of the ELCD. The recorder must have the capability to start and stop integration at points selected by the operator.

3. Reagents

3.1 Sampling.

3.1.1 Polyethylene Glycol (PEG). Ninety-eight percent pure with an average molecular weight of 400. Before using the PEG, remove any organic compounds that might be detected as volatile organics by heating it to 200 °C and purging it with nitrogen at a flow rate of 1 to 2 l/min for 2 hours.

3.2 Analysis.

3.2.1 Sample Separation. The following are required for the sample purging step:

3.2.1.1 PEG. Same as Section 3.1.1.

3.2.1.2 Purging Gas. Zero grade nitrogen (N_2), containing less than 1 ppm carbon.

3.2.2 Volatile Organic Measurement. The following are required for measuring the volatile organic concentration:

3.2.2.1 Hydrogen (H_2). Zero grade H_2, 99.999 percent pure.

3.2.2.2 Combustion Gas. Zero grade air or oxygen as required by the FID.

3.2.2.3 FID Calibration Gas. Pressurized gas cylinder containing 25 percent propane and 1 percent 1,1-dichloroethylene by volume in nitrogen.

3.2.2.4 Water. Deionized distilled water that conforms to American Society for Testing and Materials Specification D 1193–74, Type 3, is required for analysis. At the option of the analyst the $KMnO_4$ test for oxidizable organic matter may be omitted when high concentrations are not expected to be present.

3.2.2.5 N-Propanol. ACS grade or better. Electrolyte Solution. For use in the conductivity detector.

4.0 Procedure

4.1 Sampling.

4.1.1 Sampling Plan Design and Development. Use the procedures in chapter nine of the Office of Solid Waste's publication, Test Methods for Evaluating Solid Waste, third edition (SW–846), as guidance in developing a sampling plan.

4.1.2 Waste in Enclosed Pipes.

4.1.2.1 Sample as close as practical to the point of waste generation in order to minimize the loss of organics. Assemble the sampling apparatus as shown in Figure 4. Install the static mixer in the process line or in a by-pass line. Locate the tap within two pipe diameters of the static mixer outlet.

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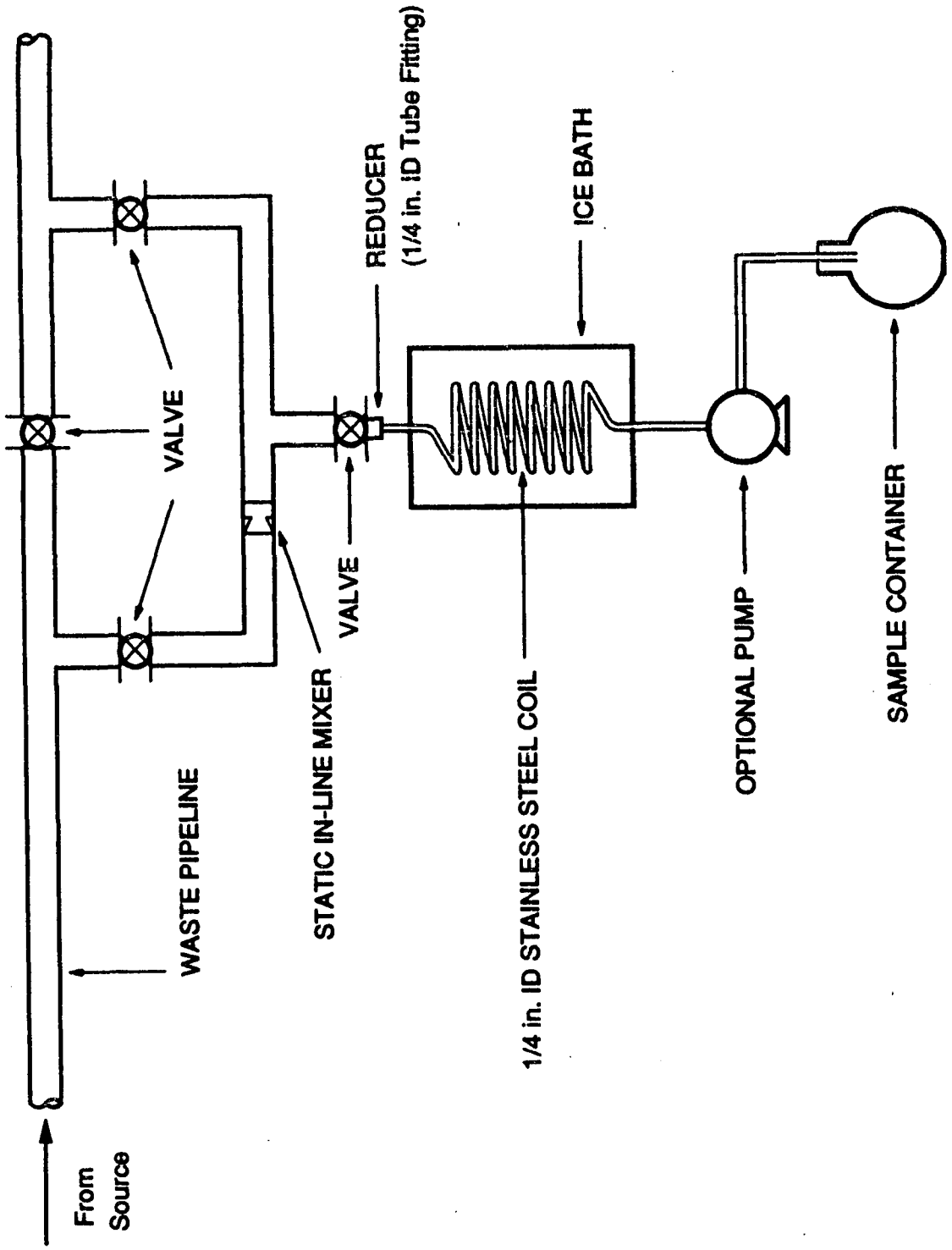

Figure 4. Schematic of Sampling Apparatus for Enclosed Pipe

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4.1.2.2 Prepare the sampling containers as follows: Pour into the container an amount of PEG equal to the total volume of the sample container minus 10 ml. PEG will reduce but not eliminate the loss of organic compounds during sample collection. Weigh the sample container with the screw cap, the PEG, and any labels to the nearest 0.01 g and record the weight (m_{st}). Before sampling, store the containers in an ice bath until the temperature of the PEG is less than 40 °F.

4.1.2.3 Begin sampling by purging the sample lines and cooling coil with at least four volumes of waste. Collect the purged material in a separate container and dispose of it properly.

4.1.2.4 After purging, stop the sample flow and direct the sampling tube to a preweighed sample container, prepared as previously described in this section. Keep the tip of the tube below the surface of the PEG during sampling to minimize contact with the atmosphere. Sample at a flow rate such that the temperature of the waste is less than 10 °C. Fill the sample container and immediately cap it (within 5 seconds) so that a minimum headspace exists in the container. Store immediately in a cooler and cover with ice.

4.1.2.5 Alternative sampling techniques may be used upon the approval of the Administrator.

4.2 Sample Recovery.

4.2.1 Assemble the purging apparatus as shown in Figures 1 and 2. Adjust the purging lance so that it reaches the bottom of the chamber.

4.2.2 Remove the sample container from the cooler, and wipe the exterior of the container to remove any extraneous ice, water, or other debris. Reweigh the sample container and sample to the nearest 0.01 g, and record the weight (m_{st}). Pour the contents of the sample container into the purging flask, rinse the sample container three times with PEG, transferring the rinsings to the purging flask after each rinse. Cap purging chamber between rinses. The total volume of PEG in the purging flask shall be approximately 50 ml. Add approximately 50 ml of water.

4.3 Sample Analysis.

4.3.1 Turn on the constant temperature bath and allow the temperature to equilibrate at 75±5 °C. Turn the bypass valve so that the purge gas bypasses the purging chamber. Turn on the purge gas. Allow both the FID and the ELCD to warm up until a stable baseline is achieved on each detector. Pack the filter flask with ice. Change this after each run and dispose of the waste water properly. When the temperature of the oven reaches 75±5 C, start both integrators and record baseline. After 1 min, turn the bypass valve so that the purge gas flows through the purging chamber. Continue recording the response of the FID and the ELCD. Monitor the readings of the pressure gauge and the rotameter. If the readings fall below established set points, stop the purging and determine the source of the leak before resuming.

4.3.2 As the purging continues, monitor the output of the detectors to make certain that the analysis is proceeding correctly and that the results are being properly recorded. Every 10 minutes read and record the purge flow rate, the pressure and the chamber temperature. Continue the purging for 30 minutes.

4.3.3 For each detector output, integrate over the entire area of the peak starting at 1 minute and continuing until the end of the run. Subtract the established baseline area from the peak area. Record the corrected area of the peak. See Figure 5 for an example integration.

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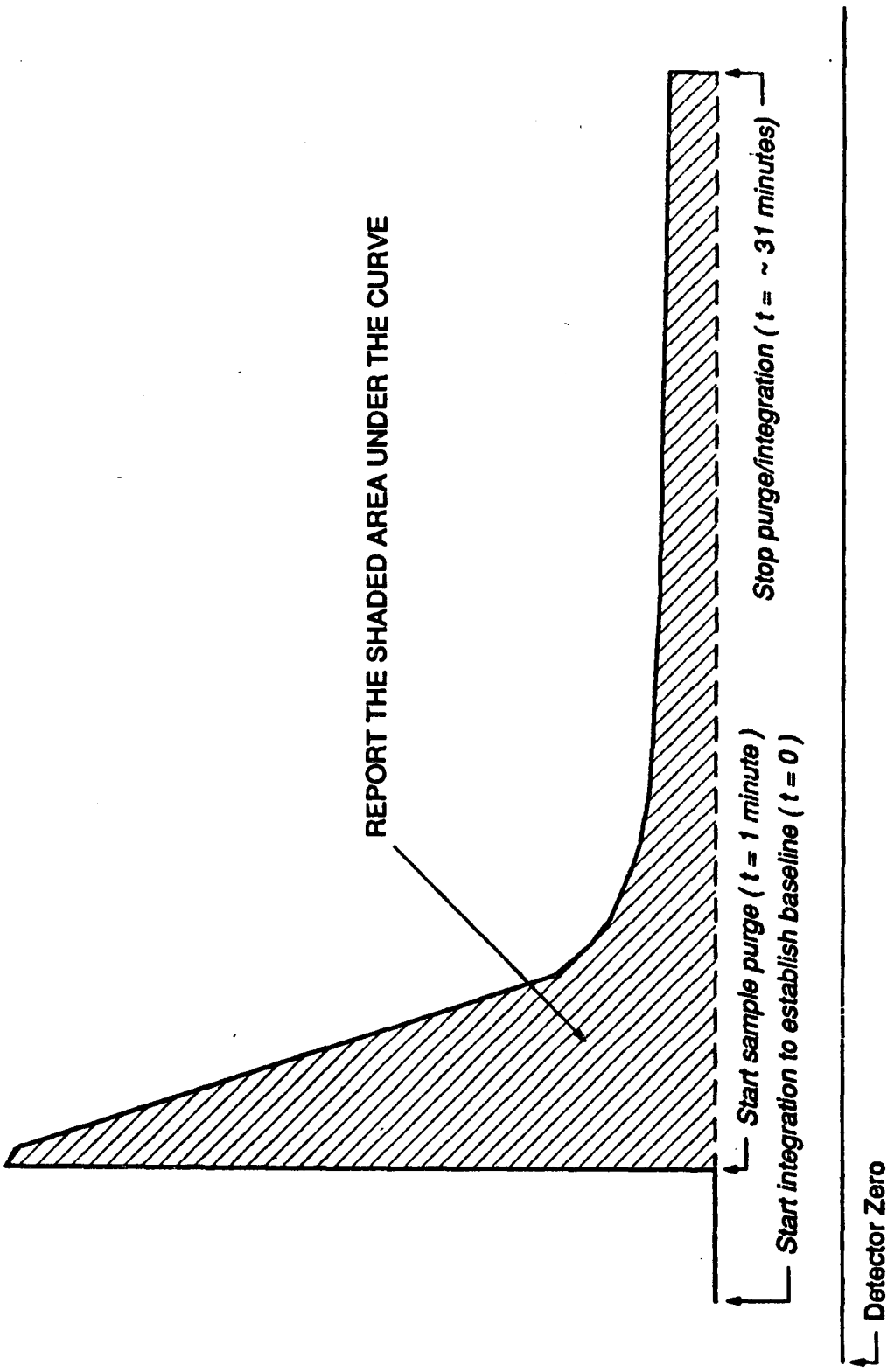

Figure 5. Sample Chromatogram and Integration for Either Detector

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4.4 Water Blank. Transfer about 60 ml of water into the purging chamber. Add 50 ml of PEG to the purging chamber. Treat the blank as described in sections 4.2 and 4.3, excluding section 4.2.2.

5. Operational Checks and Calibration

Maintain a record of performance of each item.

5.1 Initial Performance Check of Purging System. Before placing the system in operation, after a shutdown of greater than six months, and after any major modifications, conduct the linearity checks described in sections 5.1.1 and 5.1.2. Install calibration gas at the three-way calibration gas valve. See Figure 1.

5.1.1 Linearity Check Procedure. Using the calibration standards described in section 3.2.2.3 and by varying the injection time, it is possible to calibrate at multiple concentration levels. Use Equation 3 to calculate three sets of calibration gas flow rates and run times needed to introduce a total methane mass (m_{co}) of 1, 5, and 10 mg into the system (low, medium, and high FID calibration, respectively). Use Equation 4 to calculate three sets of calibration gas flow rates and run times needed to introduce a total chloride mass (m_{ch}) of 1, 5, and 10 mg into the system (low, medium and high ELCD calibration, respectively). With the purging system (low, medium and high ELCD calibration, respectively. With the purging system operating as in section 4.3, allow the FID and the ELCD to establish a stable baseline. Set the secondary pressure regulator of the calibration gas cylinder to the same pressure as the purge gas cylinder and set the proper flow rate with the calibration flow controller (see Figure 1). The calibration gas flow rate can be measured with a flowmeter attached to the vent position of the calibration gas valve. Set the four-way bypass valve to standby position so the calibration gas flows through the coalescing filter only. Inject the calibration gas by turning the calibration gas valve from vent position to inject position. Continue the calibration gas flow for the appropriate period of time before switching the calibration valve to vent position. Continue recording the response of the FID and the ELCD for 5 min. after switching off calibration gas flow. Make triplicate injections of all six levels of calibration.

5.1.2 Linearity Criteria. Calculate the average response factor (Equations 5 and 6) and the relative standards deviation (RSD) (Equation 10) at each level of the calibration curve for both detectors. Calculate the overall mean of the three response factor averages for each detector. The FID linearity is acceptable if each response factor is within 5 percent of the overall mean and if the RSD for each set of triplicate injections is less than 5 percent. The ELCD linearity is acceptable if each response factor is within 10 percent of the overall mean and if the RSD for each set of triplicate injections is less than 10 percent. Record the overall mean value of the response factors for the FID and the ELCD. If the calibration for either the FID or the ELCD does not meet the criteria, correct the detector/system problem and repeat Section 5.1.1 and 5.1.2.

5.2 Daily Calibrations.

5.2.1 Daily Linearity Check. Follow the procedures outlined in Section 5.1.1 to analyze the medium level calibration for both the FID and the ELCD in duplicate at the start of the day. Calculate the response factors and the RSD's for each detector. For the FID, the calibration is acceptable if the average response factor is within 5 percent of the overall mean response factor (Section 5.1.2) and if the RSD for the duplicate injection is less than 5 percent. For the ELCD, the calibration is acceptable if the average response factor is within 10 percent of the overall mean response factor (section 5.1.2) and if the RSD for the duplicate injection is less than 10 percent. If the calibration for either the FID or the ELCD does not meet the criteria, correct the detector/system problem and repeat Sections 5.1.1 and 5.1.2.

5.2.2 Calibration Range Check.

5.2.2.1 If the waste concentration for either detector falls below the range of calibration for the detector, use the procedure outlined in Section 5.1.1 to choose 2 calibration points that bracket the new target concentration. Analyze each of these points in triplicate (as outlined in section 5.1.1) and use the criteria in section 5.1.2 to determine the linearity of the detector in this "mini-calibration" range.

5.2.2.2 After the initial linearity check of the mini-calibration curve, it is only necessary to test one of the points in duplicate for the daily calibration check (in addition to the points specified in section 5.2.1). The average daily mini-calibration point should fit the linearity criteria specified in section 5.2.1. If the calibration for either the FID or the ELCD does not meet the criteria, correct the detector/system problem and repeat the calibration procedure mentioned in the first paragraph of section 5.2.2. A mini-calibration curve for waste concentrations above the calibration curve for either detector is optional.

5.3 Analytical Balance. Calibrate against standard weights.

5.4 Audit Procedure. Concurrently analyze the audit sample and a set of compliance samples in the same manner to evaluate the technique of the analyst and the standards preparation. The same analyst, analytical reagents, and analytical system shall be used both for compliance samples and the EPA audit sample. If this condition is met, auditing of subsequent compliance analyses for the same enforcement agency within 30 days is not required. An audit sample set may not be used to validate different sets of compliance samples under the jurisdiction of different enforcement agencies, unless prior arrangements are made with both enforcement agencies.

5.5 Audit Samples. Audit Sample Availability. Audit samples will be supplied only to enforcement agencies for compliance tests. The availability of audit samples may be obtained by writing: Source Test Audit Coordinator (MD-77B), Quality Assurance Division, Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

or by calling the Source Test Audit Coordinator (STAC) at (919) 541-7834. The request for the audit sample must be made at least 30 days prior to the scheduled compliance sample analysis.

5.6 Audit Results. Calculate the audit sample concentration according to the calculation procedure described in the audit instructions included with the audit sample. Fill in the audit sample concentration and the analyst's name on the audit response form included with the audit instructions. Send one copy to the EPA Regional Office or the appropriate enforcement agency and a second copy to the STAC. The EPA Regional Office or the appropriate enforcement agency will report the results of the audit to the laboratory being audited. Include this response with the results of the compliance samples in relevant reports to the EPA Regional Office or the appropriate enforcement agency.

6.0 Calculations.

6.1 Nomenclature.

A_b = Area under the water blank response curve, counts.

A_c = Area under the calibration response curve, counts.

A_s = Area under the sample response curve, counts.

C = Concentration of volatile organics in the sample, ppmw.

C_c = Concentration of carbon, as methane, in the calibration gas, mg/L

C_h = Concentration of chloride in the calibration gas, mg/L

DR_t = Average daily response factor of the FID, mg CH_4/counts.

DR_{th} = Average daily response factor of the ELCD, mg Cl^-/counts.

m_{co} = Mass of carbon, as methane, in a calibration run, mg.

m_{ch} = Mass of chloride in a calibration run, mg.

m_s = Mass of the waste sample, g.

m_{sc} = Mass of carbon, as methane, in the sample, mg.

m_{sf} = Mass of sample container and waste sample, g.

m_{sh} = Mass of chloride in the sample, mg.

m_{st} = Mass of sample container prior to sampling, g.

m_{vo} = Mass of volatile organics in the sample, mg.

P_p = Percent propane in calibration gas (l/l)

P_{vc} = Percent 1,1-dichloroethylene in calibration gas (l/l)

Q_c = Flow rate of calibration gas, l/min.

t_c = Length of time standard gas is delivered to the analyzer, min.

6.2 Concentration of Carbon, as Methane, in the Calibration Gas.

$$C_c = (19.681 \times P_p) + (13.121 \times P_{vc}) \quad \text{Eq. 1}$$

6.3 Concentration of Chloride in the Calibration Gas.

$$Ch = 28.998 \times P_{vc} \quad \text{Eq. 2}$$

6.4 Mass of Carbon, as Methane, in a Calibration Run.

$$m_{co} = C_c \times Q_c \times t_c \quad \text{Eq. 3}$$

6.5 Mass of Chloride in a Calibration Run.

$$m_{ch} = C_h \times Q_c \times t_c \quad \text{Eq. 4}$$

6.6 FID Response Factor, mg/counts.

$$R_t = m_{co}/A_c \quad \text{Eq. 5}$$

6.7 ELCD Response Factor, mg/counts.

$R_{th} = m_{ch}/A_c$ Eq. 6

6.8 Mass of Carbon, as Methane, in the Sample.

$m_{sc} = DR_t (A_s - A_b)$ Eq. 7

6.9 Mass of Chloride in the Sample.

$m_{sh} = DR_{th} (A_s - A_b)$ Eq. 8

6.10 Mass of Volatile Organics in the Sample.

$m_{vo} = m_{sc} + m_{sh}$ Eq. 9

6.11 Relative Standard Deviation.

$$RSD = 100/\bar{x}[\sum_{i=1}^{n} (x_i - \bar{x})^2/(n-1)]^{1/2} \quad \text{Eq. 10}$$

6.12 Mass of Sample.

$m_s = m_{sf} - m_{st}$ Eq. 11

6.13 Concentration of Volatile Organics in Waste.

$C = (m_{vo} \times 1000)/m_s$ Eq. 12

Method 25E—Determination of Vapor Phase Organic Concentration in Waste Samples

Introduction

Performance of this method should not be attempted by persons unfamiliar with the operation of a flame ionization detector (FID) nor by those who are unfamiliar with source sampling because knowledge beyond the scope of this presentation is required.

1. Applicability and Principle

1.1 Applicability. This method is applicable for determining the vapor pressure of waste samples from treatment, storage, and disposal facilities (TSDF).

1.2 Principle. A waste sample is collected from a source just prior to entering a tank. The headspace vapor of the sample is analyzed for carbon content by a headspace analyzer, which uses an FID.

2. Interferences

2.1 The analyst shall select the operating parameters best suited to his requirements for a particular analysis. The analyst shall produce confirming data through an adequate supplemental analytical technique and have the data available for review by the Administrator.

3. Apparatus

3.1 Sampling. The following equipment is required:

3.1.1 Sample Containers. Vials, glass, with butyl rubber septa, Perkin-Elmer Corporation Numbers 0105–0129 (glass vials), B001–0728 (gray butyl rubber septum, plug style), 0105–0131 (butyl rubber septa), or equivalent. The seal shall be made from butyl rubber. Silicone rubber seals are not acceptable.

3.1.2 Vial Sealer. Perkin-Elmer Number 105–0106, or equivalent.

3.1.3 Gas-Tight Syringe. Perkin-Elmer Number 00230117, or equivalent. pipe:

3.1.4.1 Static mixer. In-line or by-pass loop, sized so that the drop size of the dispersed phase is no greater than 1000 μm. If the mixer is installed as a by-pass loop, the entire waste stream shall be diverted through the mixer.

3.1.4.2 Tap.

3.1.4.3 Tubing. Teflon, 0.25-in. ID. Note: Mention of trade names or specific products does not constitute endorsement by the Environmental Protection Agency.

3.1.4.4 Cooling Coil. Stainless steel (304), 0.25 in.-ID, equipped with a thermocouple at the coil outlet.

3.2 Analysis. The following equipment is required:

3.2.1 Balanced Pressure Headspace Sampler. Perkin-Elmer HS–6, HS–100, or equivalent, equipped with a glass bead column instead of a chromatographic column.

3.2.2 FID. An FID meeting the following specifications is required:

3.2.2.1 Linearity. A linear response (±5 percent) over the operating range as demonstrated by the procedures established in Section 6.1.2.

3.2.2.2 Range. A full scale range of 1 to 10,000 ppm CH_4. Signal attenuators shall be available to produce a minimum signal response of 10 percent of full scale.

3.2.3 Data Recording System. Analog strip chart recorder or digital integration system compatible with the FID for permanently recording the output of the detector.

3.2.4 Thermometer. Capable of reading temperatures in the range of 30° to 60 °C with an accuracy of ±0.1 °C.

4. Reagents

4.1 Analysis. The following items are required for analysis:

4.1.1 Hydrogen (H_2). Zero grade.

4.1.2 Carrier Gas. Zero grade nitrogen, containing less than 1 ppm carbon (C) and less than 1 ppm carbon dioxide.

4.1.3 Combustion Gas. Zero grade air or oxygen as required by the FID.

4.2 Calibration and Linearity Check.

4.2.1 Stock Cylinder Gas Standard. 100 percent propane. The manufacturer shall: (a) certify the gas composition to be accurate to ±3 percent or better (see section 4.2.1.1); (b) recommend a maximum shelf life over which the gas concentration does not change by greater than ±5 percent from the certified value; and (c) affix the date of gas cylinder preparation, certified propane concentration, and recommended maximum shelf life to the cylinder before shipment to the buyer.

4.2.1.1 Cylinder Standards Certification. The manufacturer shall certify the concentration of the calibration gas in the cylinder by (a) directly analyzing the cylinder and (b) calibrating his analytical procedure on the day of cylinder analysis. To calibrate his analytical procedure, the manufacturer shall use, as a minimum, a three-point calibration curve.

4.2.1.2 Verification of Manufacturer's Calibration Standards. Before using, the manufacturer shall verify each calibration standard by (a) comparing it to gas mixtures prepared in accordance with the procedure described in section 7.1 of Method 106 of part 61, Appendix B, or by (b) calibrating it against Standard Reference Materials (SRM's) prepared by the National Bureau of Standards, if such SRM's are available. The agreement between the initially determined concentration value and the verification concentration value shall be within ±5 percent. The manufacturer shall reverify all calibration standards on a time interval consistent with the shelf life of the cylinder standards sold.

5. Procedure

5.1 Sampling.

5.1.1 Sampling Plan Design and Development. Use the procedures in chapter nine of the Office of Solid Waste's publication, Test Methods for Evaluating Solid Waste, third edition (SW–846), as guidance in developing a sampling plan.

5.1.2 Sample according to the procedures in chapter nine of SV–846, or, if sampling from an enclosed pipe, sample according to the procedures described below.

5.1.2.1 The sampling apparatus designed to sample from an enclosed pipe is shown in Figure 1, and consists of an in-line static mixer, a tap, a cooling coil immersed in an ice bath, a flexible Teflon tube connected to the outlet of the cooling coil, and a sample container.

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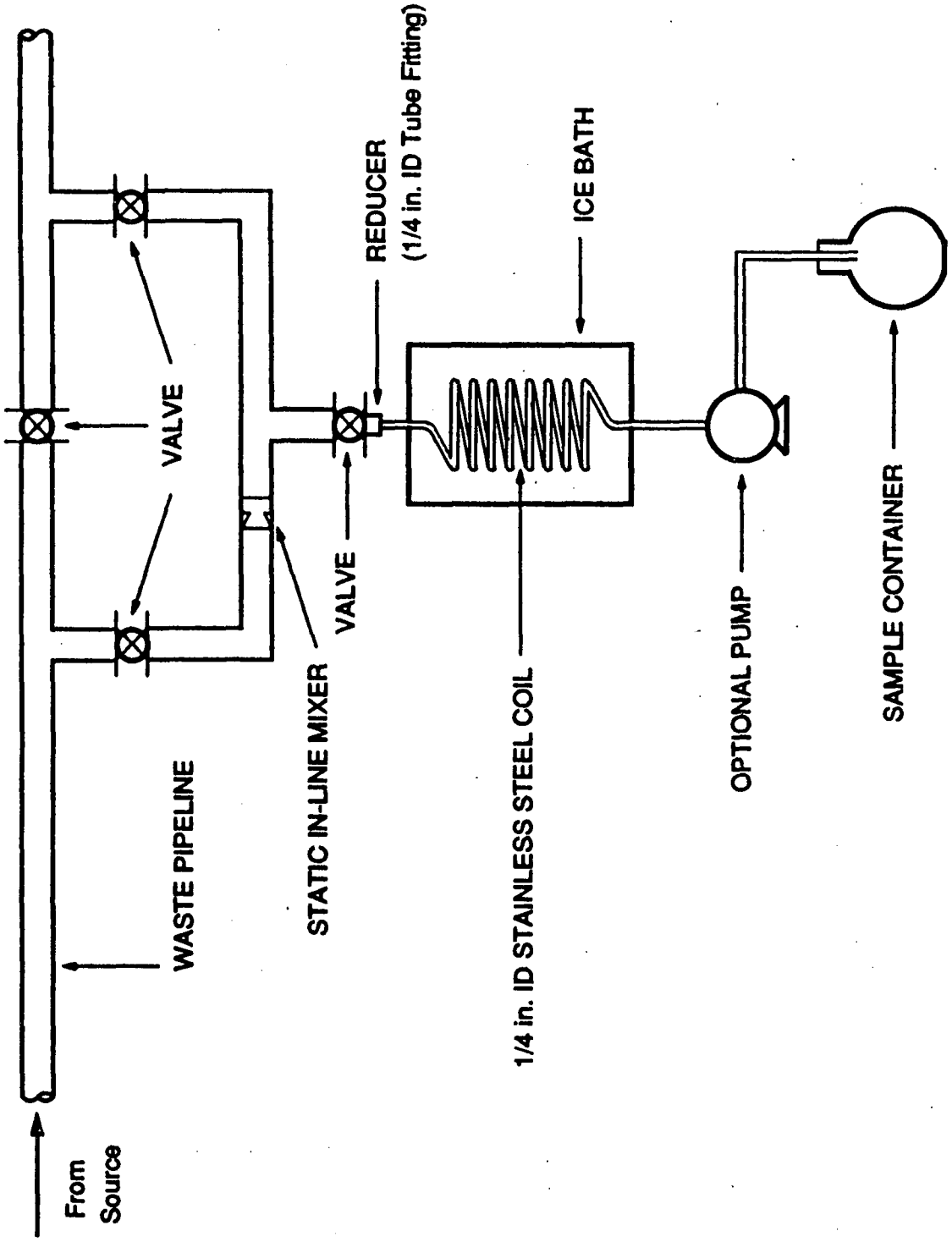

Figure 1. Schematic of Sampling Apparatus for Enclosed Pipe

BILLING CODE 6560-50-C

Locate the tap within two pipe diameters of the static mixer outlet. Install the static mixer in the process line or in a by-pass line.

5.1.2.2 Begin sampling by purging the sample lines and cooling coil with at least four volumes of waste. Collect the purged material in a separate container. Consider the purged material hazardous waste and dispose of it properly.

5.1.2.3 After purging, stop the sample flow and transfer the Teflon sampling tube to a sample container. Sample at a flow rate such that the temperature of the waste is <10 °C (<50 °F). Fill the sample container halfway (±5 percent) and cap it within 5 seconds.

5.1.2.4 Store the collected samples in ice or a refrigerator until analysis.

5.1.2.5 Alternative sampling techniques may be used upon the approval of the Administrator.

5.2 Analysis.

5.2.1 Allow one hour for the headspace vials to equilibrate at the temperature specified in the regulation. Allow the FID to warm up until a stable baseline is achieved on the detector.

5.2.2 Check the calibration of the FID daily using the procedures in Section 6.1.2.

5.2.3 Follow the manufacturer's recommended procedures for the normal operation of the headspace sampler and FID.

5.2.4 Use the procedures in sections 7.4 and 7.5 to calculate the vapor phase organic vapor pressure in the samples.

5.2.5 Monitor the output of the detector to make certain that the results are being properly recorded.

6. Operational Checks and Calibration

Maintain a record of performance of each item.

6.1 Use the procedures in section 6.1.1 to calibrate the headspace analyzer and FID and check for linearity before the system is first placed in operation, after any shutdown longer than 6 months, and after any modification of the system.

6.1.1 Calibration and Linearity. Use the procedures in section 6.2.1 of Method 18 of part 60, appendix A, to prepare the standards and calibrate the flowmeters, using propane as the standard gas. Fill the calibration standard vials halfway (±5 percent) with deionized water. Purge and fill the airspace calibration standards in triplicate at concentrations that will bracket the applicable cutoff. For a cutoff of 5.2 kPa (0.75 psi), prepare nominal concentrations of 30,000, 50,000, and 70,000 ppm as propane. For a cutoff of 27.6 kPa (4.0 psi), prepare nominal concentrations of 200,000, 300,000, and 400,000 ppm as propane.

6.1.1.1 Use the procedures in section 5.2.3 to measure the FID response of each standard. Use a linear regression analysis to calculate the values for the slope (k) and the y-intercept (b). Use the procedures in sections 7.2 and 7.3 to test the calibration and the linearity.

6.1.2 Daily FID Calibration Check. Check the calibration at the beginning and at the end of the daily runs by using the following procedures. Prepare two calibration standards at the nominal cutoff concentration using the procedures in section 6.1.1. Place one at the beginning and one at the end of the daily run. Measure the FID response of the daily calibration standard and use the values for k and b from the most recent calibration to calculate the concentration of the daily standard. Use an equation similar to 25E-2 to calculate the percent difference between the daily standard and C_s. If the difference is within 5 percent, then the previous values for k and b may be used. Otherwise, use the procedures in section 6.1.1 to recalibrate the FID.

7. Calculations

7.1 Nomenclature.

A=Measurement of the area under the response curve, counts.

b=y-intercept of the linear regression line.

C_s=Measured vapor phase organic concentration of sample, ppm as propane.

C_{ma}=Average measured vapor phase organic concentration of standard, ppm as propane.

C_m=Measured vapor phase organic concentration of standard, ppm as propane.

C_s=Calculated standard concentration, ppm as propane.

k=Slope of the linear regression line.

P_{bar}=Atmospheric pressure at analysis conditions, mm Hg (in. Hg).

p^*=Organic vapor pressure in the sample, kPa (psi).

β=1.333×10−7 kPa/[(mm Hg) (ppm)], (4.91×10−7 psi/[(in. Hg) (ppm)])

7.2 Linearity. Use the following equation to calculate the measured standard concentration for each standard vial.

$C_m = k A + b$ Eq. 25E-1

7.2.1 Calculate the average measured standard concentration (C_{ma}) for each set of triplicate standards and use the following equation to calculate the percent difference between C_{ma} and C_s.

$$\text{Percent Difference} = \frac{C_s - C_{ma}}{C_s} \times 100$$

Eq. 25E-2

The instrument linearity is acceptable if the percent difference is within five for each standard.

7.3. Relative Standard Deviation (RSD). Use the following equation to calculate the RSD for each triplicate set of standards.

$$RSD = \frac{100}{C_{ma}} \frac{\Sigma(C_m - C_{ma})^2}{n-1}$$

Eq. 25E-3

The calibration is acceptable if the RSD is within five for each standard concentration.

7.4 Concentration of organics in the headspace. Use the following equation to calculate the concentration of vapor phase organics in each sample.

$C_s = k A + b$ Eq. 25E-4

7.5 Vapor Pressure of Organics in the Headspace Sample. Use the following equation to calculate the vapor pressure of organics in the sample.

$p^* = \beta P_{bar} C_s$ Eq. 25E-5

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921-6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

2. Section 260.10 is amended by adding the following definitions in alphabetical order:

§ 260.10 Definitions.

* * * * *

Cover means a device or system which is placed on or over a waste being managed in a hazardous waste management unit so that the entire waste surface area is enclosed and sealed to minimize air emissions. A cover may have openings necessary for operation, inspection, and maintenance of the hazardous waste management unit such as access hatches, sampling ports, and gauge wells, provided that each opening is closed and sealed when not in use. Examples of covers include a fixed roof installed on a tank, a floating membrane cover installed on a surface impoundment, a lid installed on a container, and an air-supported enclosure installed over a hazardous waste management unit.

* * * * *

External floating roof means a pontoon or double-deck type floating roof that rests on the surface of a waste being managed in a hazardous waste management unit that has no fixed roof.

* * * * *

Fixation means any physical or chemical process that either reduces the mobility of hazardous constituents in a waste or eliminates free liquids as determined by Test Method 9095 (Paint Filter Liquids Test) in "Test Methods for Evaluating Solid Waste, Physical/

Chemical Methods," EPA Publication No. SW-846. Fixation includes mixing the waste with binders or fixative materials, and curing the resulting waste and binder mixture. Other synonymous terms for fixation are stabilization and solidification.

Fixed roof means a rigid cover that is installed in a stationary position so that it does not move with fluctuations in the level of the waste placed in a hazardous waste management unit.

Floating roof means a cover consisting of a rigid deck or roof that rests upon and is supported by the waste being managed in a hazardous waste management unit, and is equipped with a closure seal or seals to close the space between the cover edge and the hazardous waste management unit wall.

Floating membrane cover means a cover consisting of a synthetic flexible membrane material that rests upon and is supported by the waste being managed in a hazardous waste management unit.

* * * * *

Internal floating roof means a floating roof that rests on the surface of a waste being managed in a hazardous waste management unit that has a fixed roof.

* * * * *

Liquid-mounted seal means a foam or liquid-filled primary seal mounted in contact with the liquid continuously around the circumference of the floating roof between the hazardous waste management unit wall and the edge of the floating roof.

Loading means the placement of a waste into a hazardous waste management unit but not necessarily to the capacity of the unit (also referred to as "filling").

* * * * *

Maximum organic vapor pressure means the equilibrium partial pressure exerted by a waste at the temperature equal to (1) the highest calendar-month average temperature of the waste if the temperature of the waste in the hazardous waste management unit is maintained at a temperature above or below the ambient temperature, or (2) the local maximum monthly average temperature as reported by the National Weather Service if the temperature of the waste in the hazardous waste management unit is maintained at the ambient temperature.

* * * * *

No detectable organic emissions means no escape of organics from a device or system to the atmosphere as determined by an instrument reading less than 500 ppm by volume (ppmv) above the background level at each joint, fitting, and seal when measured by the methods specified in Reference Method 21 in 40 CFR part 60 appendix A, and by no visible openings or defects in the device or system such as rips, tears, or gaps.

* * * * *

Quiescent means a state in which a waste is managed without mixing, stirring, or shaking the waste using a device such as a mechanical mixer, agitator, aerator, or any system which creates flow induced turbulence.

* * * * *

Vapor-mounted seal means a foam-filled primary seal mounted continuously around the circumference of the hazardous waste management unit so that there is an annular vapor space underneath the seal. The annular vapor space is bounded by the bottom of the primary seal, the unit wall, the liquid surface, and the floating roof.

* * * * *

Volatile organic concentration means the concentration by weight of organic compounds in a hazardous waste as determined by Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846.

Waste dilution means the intentional or unintentional reduction in the organic concentration of a hazardous waste due to mixing the hazardous waste together with another hazardous waste, solid waste, or nonhazardous waste for any purpose.

* * * * *

3. Paragraph (a) of § 260.11 is amended by adding the following references:

§ 260.11 References.

(a) * * *

"ASTM Standard Test Method for Vapor Pressure—Temperature Relationship and Initial Decomposition Temperature for Liquids by Isoteniscope," ASTM Standard D-2879-83, available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, Pennsylvania 19103;

* * * * *

"Evaporation Loss from External Floating Roof Tanks," API Bulletin 2517 [Second Edition (February 1980)], available from the American Petroleum Institute, 1220 L St., NW., Washington, DC 20037.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

4. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924 and 6925.

Subpart B—General Facility Standards

§ 264.13 [Amended]

5-7. In § 264.13, paragraph (b)(6) is amended by adding "264.1082," after the phrase "as specified in §§ 264.17, 264.314, 264.341, 264.1034(d), 264.1063(d),".

8. In § 264.13, paragraph (b)(8) is added to read as follows:

§ 264.13 General waste analysis.

* * * * *

(b) * * *

(8) For owners and operators seeking an exception to the air emission standards of subpart CC in accordance with § 264.1081—

(i) The procedures and schedules for waste sampling and analysis, and the analysis of test data to verify the exception.

(ii) Each generator's notice and certification of the volatile organic concentration in the waste if the waste is received from off site.

* * * * *

§ 264.15 [Amended]

9. In § 264.15, paragraph (b)(4) is amended by removing the word "and" after the phrase "frequencies called for in §§ 264.174, 264.194, 264.226, 264.253, 264.254, 264.303, 264.347, 264.602, 264.1033, 264.1052, 264.1053," and inserting "264.1086, 264.1087, and 264.1090(b)," after "264.1058,".

Subpart E—Manifest System, Recordkeeping, and Reporting

10. Section 264.73 is amended by revising paragraphs (b)(3) and (b)(6) to read as follows:

§ 264.73 Operating record.

* * * * *

(b) * * *

(3) Records and results of waste determinations performed as specified in §§ 264.13, 264.17, 264.314, 264.341, 264.1034, 264.1063, 264.1082, 268.4(a), and 268.7 of this chapter.

* * * * *

(6) Monitoring, testing or analytical data, and corrective action where required by subpart F and §§ 264.226, 264.253, 264.254, 264.276, 264.278, 264.280,

264.303, 264.309, 264.347, 264.602, 264.1034(c)–(f), 264.1035, 264.1063(d)–(i), 264.1064, 264.1088, and 264.1090(b).

* * * * *

11. Section 264.77 is amended by revising paragraph (c) to read as follows:

§ 264.77 Additional reports.

* * * * *

(c) As otherwise required by subparts F, K through N, AA, BB, and CC.

Subpart I—Use and Management of Containers

12. Section 264.179 is added to read as follows:

§ 264.179 Air Emission Standards.

Containers shall be managed in compliance with the air emission standards provided in subpart CC of this part.

Subpart J—Tank Systems

13. Section 264.200 is added to read as follows:

§ 264.200 Air emission standards.

Tanks shall be managed in compliance with the air emission standards provided in subpart CC of this part.

Subpart K—Surface Impoundments

14. Section 264.232 is added to read as follows:

§ 264.232 Air emission standards.

Surface impoundments shall be managed in compliance with the air emission standards provided in subpart CC of this part.

Subpart X—Miscellaneous Units

§ 264.601 [Amended]

15. The introductory text of § 264.601 is amended by inserting the words "and subparts AA through CC" after "subparts I through O".

Subpart AA—Air Emission Standards for Process Vents

16. Section 264.1033 is amended by adding paragraph (m) to read as follows:

§ 264.1033 Standards: Closed-vent systems and control devices.

* * * * *

(m) The owner or operator using a carbon adsorption system shall certify that all carbon removed from a carbon adsorption system to comply with § 264.1033(g)–(h) of this part is either:

(1) Regenerated or reactivated by a process that minimizes emissions of organics to the atmosphere. (Note: EPA interprets "minimizes" as used in this paragraph to include the application of effective control devices such as those required in this subpart); or

(2) Incinerated by a process that achieves the performance standards specified in subpart O of this part.

17. In 40 CFR part 264, subpart CC is added to read as follows:

Subpart CC—Air Emission Standards for Tanks, Surface Impoundments, and Containers

Sec.

Subpart CC—Air Emission Standards for Tanks, Surface Impoundments, and Containers

§ 264.1080 Applicability.

(a) The regulations in this subpart apply to owners and operators of facilities that treat, store, or dispose of hazardous waste in units that are subject to subparts I, J, K, and X of this part except as provided in § 264.1. of this part.

(b) For owners or operators meeting the applicability requirement in paragraph (a) of this section who received a final permit under section 3005 of RCRA prior to the effective date of this rule (6 months after the promulgation date of the final rule):

(1) The requirements of this subpart shall be incorporated into the permit when the permit is reissued under § 124.15 or reviewed under § 270.50(d).

(2) Until permit reissue or review, the requirements of subpart CC in part 265 of this title apply.

§ 264.1081 Exceptions to the standards.

(a) A hazardous waste management unit is excepted from standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart provided that the owner or operator meets all of the following requirements:

(1) Determines in accordance with the procedures specified in § 264.1082 of this subpart that the waste placed in the hazardous waste management unit at all times has a volatile organic concentration less than 500 parts per million by weight (ppmw) at either:

(i) A point before the waste is first exposed to the atmosphere such as in enclosed pipe or other closed system that is used to transfer the waste after generation to the first hazardous waste management unit; or

(ii) The outlet from a treatment unit that:

(A) Removes or destroys organics in the waste using a means other than by waste dilution or evaporation into the atmosphere; and

(B) Is in compliance with all applicable standards in this part.

(2) Performs the waste determination required by paragraph (a)(1) of this section at least once per year and whenever the process, operation, or source generating the waste changes in such a manner that the volatile organic concentration of the waste may change.

(b) An owner or operator may place waste in a hazardous waste management unit without the control equipment specified in §§ 264.1083, 264.1084, and 264.1085 of this subpart provided that the owner or operator provides documentation certifying that the waste placed in the hazardous waste management unit complies with the applicable treatment standards for organic-containing waste pursuant to the requirements of subpart D in part 268 of this title.

§ 264.1082 Waste determinations.

(a) Waste volatile organic concentration determination for an exception under § 264.1081(a)(1)(i) of this subpart.

(1) The owner or operator shall use either direct measurement, knowledge of the waste, or waste certification to determine the volatile organic concentration of the waste in accordance with the following requirements:

(i) *Direct measurement.* (A) All waste samples shall be collected at a point before the waste is first exposed to the atmosphere and at a time when the maximum volatile organic concentration in the waste stream is expected to occur. The sampling program shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846.

(B) A minimum of four representative samples shall be collected and analyzed using the test procedures specified in Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846; and the

calculation procedure specified in appendix X of this part.

(C) If the waste volatile organic concentration determined in paragraph (a)(1)(i)(B) of this section is less than 500 ppmw, then the waste may be placed in a hazardous waste management unit pursuant to § 264.1081(a) of this subpart.

(ii) *Knowledge of the waste.* The owner or operator shall provide sufficient information to document that the volatile organic concentration of the waste at all times is less than 500 ppmw. Examples of information that may be used include documentation that the waste is generated by a process for which no organics-containing materials are used, or the waste is generated by a process for which it previously has been determined by direct measurement at other locations using the same type of process that the waste has a volatile organic concentration less than 500 ppmw.

(iii) *Waste Certification.* If an owner or operator cannot perform the waste determination at a point before the waste is first exposed to the atmosphere because the waste is generated off site, then the owner or operator may determine the waste volatile organic concentration upon receiving the waste from the generator provided the waste is accompanied by:

(A) A notice that includes the following information:

(*1*) EPA Hazardous Waste Number,

(*2*) Manifest number associated with the shipment of hazardous waste, and

(*3*) Volatile organic concentration waste determination results obtained in accordance with the methods specified in paragraph (a)(1)(i) or (a)(1)(ii) of this section.

(B) Certification that is signed and dated by an authorized representative of the generator and states the following:

I certify under penalty of law that I personally have examined and am familiar with the waste through analysis and testing or through knowledge of the waste, and I support this certification that the waste does not exceed a volatile organic concentration of 500 ppmw. I believe that the information submitted is true, accurate, and complete. I am aware that there are significant penalties for submitting a false certification, including the possibility of a fine and imprisonment.

(2) The Regional Administrator may request at any time that the owner or operator perform a waste determination in accordance with paragraph (a)(1)(i) of this section. A result from the waste determination requested by the Regional Administrator indicating that the waste volatile organic concentration is equal to or greater than 500 ppmw shall be conclusive evidence that each hazardous waste management unit in which the waste has been placed is not excepted from standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart.

(b) Waste determination of volatile organic concentration for an exception under § 264.1081(a)(1)(ii) of this subpart.

(1) The owner or operator shall use either direct measurement or knowledge of the waste to determine the volatile organic concentration of the waste at the outlet of the treatment unit and whether waste dilution was used to achieve this concentration in accordance with the following requirements:

(i) *Direct measurement.* (A) Determination of the volatile organic concentration of the waste at the outlet from the treatment unit.

(*1*) All waste samples shall be collected at the treatment unit outlet and at a time when the maximum volatile organic concentration in the waste stream is expected to occur. The sampling program shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846.

(*2*) A minimum of four representative samples shall be collected and analyzed using the test procedures specified in Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846; and the calculation procedure specified in appendix X of this part.

(B) Determination that no waste dilution has occurred.

(*1*) Representative waste samples for each waste stream entering and exiting the treatment unit shall be collected as near in time as possible. The sampling program shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846.

(*2*) The samples shall be analyzed using the test procedures specified in Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846 to determine the volatile organic concentration of each waste stream entering and exiting the treatment unit. A weighted average volatile organic concentration for all of the waste streams entering the treatment unit shall be calculated using the procedure specified in appendix XI of this part.

(*3*) If the weighted average volatile organic concentration for all streams entering the treatment unit is greater than the volatile organic concentration for the waste stream exiting the treatment unit as determined in accordance with paragraph (b)(1)(i)(B)(*2*) of this section, then no waste dilution has occurred.

(C) If the waste volatile organic concentration at the outlet of the treatment unit as determined in paragraph (b)(1)(i)(A) of this section is less than 500 ppmw and no waste dilution has occurred as determined in paragraph (b)(1)(i)(B) of this section, then the waste may be placed in a hazardous waste management unit in accordance with § 264.1081(a) of this subpart.

(ii) *Knowledge of the waste.* The owner or operator shall provide sufficient information to document that the volatile organic concentration of the waste exiting the treatment unit is less than 500 ppmw at all times and that no waste dilution has occurred.

(2) The Regional Administrator may request at any time that the owner or operator perform a waste determination in accordance with paragraph (b)(1)(i) of this section. A result from the waste determination requested by the Regional Administrator indicating that the waste volatile organic concentration is equal to or greater than 500 ppmw or that waste dilution has occurred shall be conclusive evidence that each hazardous waste management unit in which the waste has been placed is not excepted from standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart.

(c) Waste determination of maximum organic vapor pressure for a tank having a design capacity equal to or greater than 75 m^3 in accordance with § 264.1083(b)(2) of this subpart.

(1) The owner or operator shall use either direct measurement or knowledge of the waste to determine the maximum organic vapor pressure of the waste in accordance with the following requirements:

(i) *Direct measurement.* (A) All waste samples shall be collected at the inlet to the tank. Sampling shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846.

(B) Any one of the following methods may be used to analyze the samples and compute the maximum organic vapor pressure:

(*1*) Reference Method 25E in 40 CFR part 60 appendix A or Test Method 5110

in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846;

(2) Methods described in American Petroleum Institute Bulletin 2517, "Evaporation Loss from External Floating Roof Tanks," (incorporated by reference—refer to § 260.11);

(3) Methods obtained from standard reference texts;

(4) ASTM Method 2879-83 (incorporated by reference—refer to § 260.11); or

(5) Any other method approved by the Regional Administrator.

(ii) *Knowledge of the waste.* The owner or operator shall provide sufficient information to document that the maximum organic vapor pressure at all times is less than the maximum vapor pressure limit for the appropriate tank design capacity category specified in § 264.1083(b)(2)(i)(D). Examples of information that may be used include documentation that the waste is generated by a process for which no organics-containing materials are used, or the waste is generated by a process for which at other locations it previously has been determined by direct measurement that the waste maximum organic vapor pressure is less than the maximum vapor pressure limit for the appropriate tank design capacity category specified in § 264.1083(b)(2)(i)(D) of this subpart.

(2) The Regional Administrator may request at any time that the owner or operator perform a waste determination in accordance with paragraph (c)(1)(i) of this section. A result from the waste determination requested by the Regional Administrator indicating that the waste maximum organic vapor pressure exceeds the appropriate maximum organic vapor pressure limit for the appropriate tank design capacity category specified in § 264.1083(b)(2)(i)(D) shall be conclusive evidence that each tank in which the waste has been placed is not excepted from requirements pursuant to § 264.1083(b)(1) of this subpart.

§ 264.1083 Standards: tanks.

(a) *Applicability.* This section applies to the owner or operator of a facility where hazardous waste is placed in tanks except as provided in § 264.1081 of this subpart.

(b) Design and operation of control equipment.

(1) The owner or operator shall meet one of the following control equipment requirements except as provided in paragraph (b)(2) of this section:

(i) Install, operate, and maintain a fixed roof cover and closed vent system that routes the organic vapors vented from the tank to a control device.

(A) The fixed roof shall meet the following requirements:

(1) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(2) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the tank except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(B) The closed vent system and control device shall be designed and operated in accordance with the requirements of § 264.1086 of this subpart.

(ii) Install, operate, and maintain a pressurized tank that is designed to operate at a pressure in excess of 204.9 kPa (29.7 psi) and that operates with no detectable organic emissions.

(iii) Install, operate, and maintain alternative control equipment in accordance with the requirements of § 264.1090 of this subpart.

(2) As an alternative to the control equipment specified in paragraph (b)(1) of this section, an owner or operator may install, operate, and maintain on a tank that meets all of the conditions specified in paragraph (b)(2)(i) of this section a fixed roof as specified in paragraph (b)(2)(ii) of this section.

(i) The waste placed in the tank shall meet the following conditions:

(A) The waste is quiescent at all times that the waste is managed in the tank;

(B) The waste is not managed in the tank using a waste fixation process;

(C) The waste is not managed in the tank using a process that requires the addition of heat to the waste or produces an exothermic reaction; and

(D) The waste is either:

(1) Placed in a tank having a design capacity less than 75 m^3 (19,789 gal);

(2) Placed in a tank having a design capacity greater than or equal to 75 m^3 (19,789 gal) but less than 151 m^3 (39,841 gal), and the waste has a maximum organic vapor pressure less than 27.6 kPa (4.0 psi); or

(3) Placed in a tank having a design capacity greater than or equal to 151 m^3 (39,841 gal), and the waste has a maximum organic vapor pressure less than 5.2 kPa (0.75 psi).

(ii) The fixed roof shall meet the following requirements:

(A) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(B) Each cover vent that discharges to the atmosphere shall be equipped with a pressure-relief valve, a pressure-vacuum valve, a pilot-operated relief valve, or equivalent pressure-relief device. The device shall be operated so that no detectable organic emissions occur from the vent except during periods when conditions such as filling or emptying the tank or diurnal temperature changes require venting of the tank to prevent physical damage or permanent deformation of the tank or cover.

(C) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the tank except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(3) No waste shall be placed in the tank whenever control equipment specified in paragraphs (b)(1) or (b)(2) of this section is not in operation.

(c) The owner and operator shall install, operate, and maintain enclosed pipes or other closed systems to:

(1) Transfer waste to the tank from all other hazardous waste management units subject to standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart, and

(2) Transfer waste from the tank to all other hazardous waste management units subject to standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart.

§ 264.1084 Standards: surface impoundments.

(a) Applicability. This section applies to the owner or operator of a facility where hazardous waste is placed in surface impoundments, except as provided in § 264.1081 of this subpart.

(b) Design and operation of control equipment.

(1) The owner or operator shall install, operate, and maintain on each surface impoundment a cover (e.g., air-supported structure, rigid cover) and closed vent system that routes all organic vapors vented from the surface impoundment to a control device except as provided in paragraph (b)(2) of this section:

(i) The cover shall meet the following requirements:

(A) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(B) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the surface impoundment except when it

is necessary to use the opening for waste loading, removal, inspection, or sampling, or for equipment inspection, maintenance, or repair.

(ii) The closed vent system and control device shall be designed and operated in accordance with § 264.1086 of this subpart.

(2) As an alternative to the control equipment specified in paragraph (b)(1) of this section, an owner or operator may install, operate, and maintain on a surface impoundment that meets all of the conditions specified in paragraph (b)(2)(i) of this section either a floating membrane cover as specified in paragraph (b)(2)(ii) of this section or a cover as specified in paragraph (b)(2)(iii) of this section.

(i) The waste placed in the surface impoundment shall meet the following conditions:

(A) The waste is quiescent at all times that the waste is managed in the surface impoundment;

(B) The waste is not managed in the surface impoundment using a waste fixation process;

(C) The waste is not managed in the surface impoundment using a process that requires the addition of heat to the waste or produces an exothermic reaction.

(ii) The floating membrane cover shall meet the following requirements:

(A) Be designed, constructed, and installed so that when the surface impoundment is filled to capacity, the waste surface area is covered completely;

(B) The floating membrane cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(C) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times waste is in the surface impoundment except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(D) The synthetic membrane material used for the floating membrane cover shall be either:

(*1*) High density polyethylene with a thickness no less than 2.5 mm (100 mils), or

(*2*) A material or a composite of different materials determined to have all of the following:

(*i*) Organic permeability properties that are equivalent to those of the material specified in paragraph (b)(2)(ii)(D)(*1*) of this section, and

(*ii*) Chemical and physical properties that maintain the material integrity for as long as the cover is in use. Factors that shall be considered in selecting the material include: the effects of contact with the waste managed in the impoundment, weather exposure, and cover installation and operation practices.

(iii) The cover shall meet the following requirements:

(A) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(B) The waste surface shall be completely enclosed by the cover and the air space underneath the cover shall not be vented to the atmosphere.

(3) No waste shall be placed in the surface impoundment whenever control equipment specified in paragraph (b)(1) or (b)(2) of this section is not in operation.

(c) The cover shall be used at all times that any waste is placed in the surface impoundment except during removal of treatment residues in accordance with § 268.4 of this title or closure of the surface impoundment in accordance with § 264.228 of this part.

(d) The owner or operator shall install, operate, and maintain enclosed pipes or other closed systems to:

(1) Transfer waste to the surface impoundment from all other hazardous waste management units subject to standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart, and

(2) Transfer waste from the surface impoundment to all other hazardous waste management units subject to standards pursuant to §§ 264.1083, 264.1084, and 264.1085 of this subpart.

§ 264.1085 Standards: containers.

(a) *Applicability.* This section applies to the owner or operator of a facility where hazardous waste is placed in containers except as provided in § 264.1081 of this subpart.

(b) *Design and operation of control equipment.* (1) The owner or operator shall install, operate, and maintain a cover on each container used to handle, transfer, or store waste in accordance with the following requirements:

(A) The cover and all cover openings (e.g., bungs, hatches, and sampling ports) shall be designed to operate with no detectable organic emissions.

(B) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the container except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(2) Treatment of a waste in a container by either waste fixation, a process that requires the addition of heat to the waste, or a process that produces an exothermic reaction shall be performed by the owner or operator in a manner such that during the treatment process whenever it is necessary for the container to be open, the container is located under a cover (e.g., hood, enclosure) with a closed vent system that routes all organic vapors vented from the container to a control device.

(i) The cover and all cover openings (e.g., doors, hatches) shall be designed to operate with no detectable organic emissions.

(ii) The closed vent system and control device shall be designed and operated in accordance with § 264.1086 of this subpart.

(3) The owner or operator shall load pumpable waste into a container using a submerged fill pipe placed so that the outlet extends to within two fill pipe diameters of the bottom of the container while the container is being loaded. During loading of the waste, the cover shall remain in place and all cover openings shall be maintained in a closed, sealed position except for those cover openings required for the submerged fill pipe and for venting of the container to prevent physical damage or permanent deformation of the container or cover.

§ 264.1086 Standards: closed vent systems and control devices.

(a) Applicability. This section applies to the owner or operator of a facility where a closed vent system and control device is used to comply with standards pursuant to §§ 264.1083, 264.1084, or 264.1085 of this subpart.

(b) The owner or operator shall properly design, install, operate, and maintain each closed vent system and control device in accordance with the following requirements:

(1) The closed vent system shall operate with no detectable organic emissions at all times that any waste is in the hazardous waste management unit being controlled.

(2) The control device shall operate at the conditions that reduce the organics in the gas stream vented to it by at least 95 percent by weight or at the conditions specified in § 264.1033 (c) and (d) of this part at all times that any waste is in the hazardous waste management unit being controlled.

(c) The owner or operator shall determine that each control device achieves the appropriate conditions specified in paragraph (b)(2) of this

section in accordance with the following requirements:

(1) The owner or operator of a control device other than a flare or carbon adsorption system shall use one of the following methods:

(i) Engineering calculations in accordance with requirements specified in § 264.1035(b)(4)(iii) of this part; or

(ii) Performance tests performed using the test methods and procedures in accordance with requirements specified in § 264.1034 (c)(1)–(c)(4) of this part.

(2) The owner or operator of a flare shall use the method specified in § 264.1033(e) of this part.

(3) The owner or operator of a carbon adsorption system shall use either one of the methods specified in paragraph (c)(1)(i) or (c)(1)(ii) of this section based on the total quantity of organics vented to the atmosphere from all carbon adsorption system equipment that is used for organic adsorption, organic desorption or carbon regeneration, organic recovery, and carbon disposal.

(d) If the owner or operator and the Regional Administrator do not agree on a determination using engineering calculations of a control device organic emission reduction or, for external combustion devices, organic compound concentrations, then the disagreement shall be resolved based on the results of performance tests performed by the owner or operator using the test methods and procedures as required in § 264.1034 (c)(1)–(c)(4) of this part. The Regional Administrator may elect to have an authorized representative observe the performance tests.

(e) The owner or operator using a carbon adsorption system shall comply with § 264.1033 (g) and (h) of this part, and shall certify that all carbon removed from the carbon adsorption system is either:

(1) Regenerated or reactivated by a process that minimizes emissions of organics to the atmosphere. (**Note:** EPA interprets "minimizes" as used in this paragraph to include the application of effective control devices such as those required in this subpart); or

(2) Incinerated by a process that achieves the performance standards specified in subpart O of this part.

§ 264.1087 Monitoring and inspection requirements.

(a) Applicability. This section applies to the owner or operator of a facility where control equipment is used pursuant to §§ 264.1083, 264.1084, or 264.1085 of this subpart.

(b) The owner or operator shall monitor and inspect each cover, except for internal floating roofs and external floating roofs complying with § 264.1090, in accordance with the following requirements:

(1) The owner or operator shall visually inspect each cover initially upon installation of the cover and thereafter at least once per week. The visual inspection shall include inspection of fabric and sealing material on all openings for evidence of visible defects such as rips, gaps, or tears. If visible defects are observed during an inspection, then a leak is detected and the leak shall be repaired in accordance with paragraph (b)(3) of this section.

(2) The owner or operator shall monitor each cover in the following manner:

(i) Each cover connection and seal shall be monitored initially upon installation of the cover and thereafter at least once every six months in accordance with Reference Method 21 in 40 part 60 appendix A.

(ii) If the monitoring instrument indicates detectable emissions (i.e., a concentration above 500 ppmv), then a leak is detected and the leak shall be repaired in accordance with paragraph (b)(3) of this section.

(iii) Seals on floating membrane covers shall be monitored around the entire perimeter of the cover at locations spaced no greater than 3 meters apart.

(3) When a leak is detected by either of the methods specified in paragraphs (b)(1) or (b)(2) of this section, the owner or operator shall repair the leak in the following manner:

(i) Repair of the leak shall be completed as soon as practicable, but no later than 15 calendar days after the leak is detected. If repairs cannot be completed within 15 days except as provided in paragraph (b)(3)(iii) of this section, the owner or operator shall not add waste to the hazardous waste management unit until the repair is complete.

(ii) A first attempt at repair of each leak shall be made no later than 5 calendar days after the leak is detected.

(iii) Repair of control equipment installed to comply with § 264.1084(b) of this subpart and for which leaks have been detected may be delayed beyond 15 calendar days if the owner or operator documents that the repair cannot be completed without a complete or partial facility or surface impoundment shutdown and that delaying the repair would not cause the control equipment to be significantly less protective of human health and the environment. Repair of this control equipment shall be completed before the end of the next facility or surface impoundment shutdown.

(c) The owner or operator shall monitor and inspect each closed vent system and control device in accordance with the following requirements:

(1) The owner or operator shall monitor each control device in accordance with §§ 264.1033(f)(1) and 264.1033 (f)(2) of this part. The owner or operator shall inspect at least once each operating day all data recorded by the control device monitoring equipment (e.g., temperature monitors) to check that the control devices are being operated in compliance with this subpart.

(2) The owner or operator shall visually inspect each closed vent system and control device installed initially upon installation of the equipment and thereafter at least once per week. The visual inspection shall include inspection of ductwork and piping and their connections to covers and control devices for evidence of visible defects such as holes in ductwork or piping and loose connections. If visible defects are observed during an inspection, the closed vent system and control device shall be repaired in accordance with paragraph (c)(4) of this section.

(3) The owner or operator shall monitor each closed vent system and control device in the following manner:

(i) Each cover connection and seal shall be monitored initially upon installation of the equipment and thereafter at least once every year in accordance with Reference Method 21.

(ii) If the monitoring instrument indicates detectable emissions (i.e., a concentration above 500 ppmv), then a leak is detected and the leak shall be repaired in accordance with paragraph (c)(4) of this section.

(4) When a defect or leak is detected by either of the methods specified in paragraph (c)(2) or (c)(3) of this section, the owner or operator shall repair the defect or leak in the following manner:

(i) Repair of the defect or leak shall be completed as soon as practicable, but no later than 15 calendar days after the defect or leak is detected. If repairs cannot be completed within 15 days, then the owner or operator shall not add waste to the hazardous waste management unit until the repair is complete.

(ii) A first attempt at repair of each defect or leak shall be made no later than 5 calendar days after the defect or leak is detected.

(d) The owner or operator shall develop and follow a written schedule for all monitoring and inspection requirements of this section used to comply with this subpart. The owner or operator shall incorporate this schedule into the facility inspection plan described in § 264.15 of this part.

§ 264.1088 Recordkeeping requirements.

(a) An owner or operator placing waste in a hazardous waste management unit using control equipment pursuant to §§ 264.1083, 264.1084, or 264.1085 of this subpart shall record the following information:

(1) Engineering design documentation for each cover that includes:

(i) Cover type,

(ii) Cover manufacturer's name and model number,

(iii) Cover dimensions,

(iv) Materials used to fabricate cover,

(v) Mechanism used to install cover on the waste management unit and seal the cover perimeter,

(vi) Type, size, and location of each cover opening, and

(vii) Mechanism used to close and seal each cover opening identified in paragraph (a)(1)(vi) of this section

(2) Documentation for each closed vent system and control device that includes:

(i) Certification that is signed and dated by the owner or operator stating that the control device is designed to operate at the performance level documented by paragraph (a)(2)(ii) or (a)(2)(iii) of this section when the hazardous waste management unit is or would be operating at capacity or the highest level reasonably expected to occur.

(ii) If engineering calculations are used, then design documentation as specified in § 264.1035(b)(4) of this part. Documentation provided by the control device manufacturer or vendor that describes the control device design in accordance with § 264.1035(b)(4)(iii) of this part and certifies that the control equipment meets the specifications may be used to comply with this requirement.

(iii) If performance tests are used, then a performance test plan as specified in § 264.1035(b)(3) of this part and all test results.

(iv) Information as required by § 264.1035 (c)(1) and (c)(2).

(3) Records for all visual inspections conducted in accordance with § 264.1087 of this subpart.

(4) Records for all Reference Method 21 monitoring conducted in accordance with § 264.1087 of this subpart.

(5) Records for all continuous monitoring conducted in accordance with § 264.1087 of this subpart.

(b) An owner or operator placing waste having a volatile organic concentration equal to or greater than 500 ppmw in a tank pursuant to § 264.1083(b)(2) of this subpart shall record the following information for each tank:

(1) Date, time, and location each waste sample is collected for direct measurement waste determination of maximum organic vapor pressure in accordance with § 264.1082 of this subpart.

(2) Results of each waste determination for maximum organic vapor pressure performed in accordance with § 264.1082(c) of this subpart.

(3) Records specifying the tank dimensions and design.

(4) If the maximum organic vapor pressure of the waste placed in the tank exceeds the maximum organic vapor pressure limit for the tank's design capacity category specified in § 264.1083(b)(2)(i)(D) of this subpart, then an explanation of the reason or reasons why the waste was not managed in accordance with this subpart.

(c) An owner or operator placing waste in a hazardous waste management unit pursuant to § 264.1081(a)(1)(i) of this subpart shall record the following information for each waste management unit:

(1) Date, time, and location that each waste sample is collected for direct measurement waste determination of volatile organic concentration in accordance with § 264.1081(a) of this subpart.

(2) All waste determination volatile organic concentration results from either direct measurements performed in accordance with § 264.1082(a)(1)(i) of this subpart or knowledge documented in accordance with § 264.1082(a)(1)(ii) of this subpart.

(3) If the volatile organic concentration of the waste placed in the waste management unit is equal to or greater than 500 ppmw, then an explanation of the reason or reasons why the waste was not managed in accordance with this subpart.

(d) An owner or operator placing waste in a hazardous waste management unit pursuant to § 264.1081(a)(1)(ii) of this subpart shall record the following information for each waste management unit:

(1) Date, time, and location that each waste sample is collected for direct measurement determination of volatile organic concentration in accordance with § 264.1081(a) of this subpart.

(2) All waste determination volatile organic concentration results from either direct measurements performed in accordance with § 264.1082(b)(1)(i) of this subpart or knowledge documented in accordance with § 264.1082(b)(1)(ii) of this subpart.

(3) If the volatile organic concentration of the waste placed in the waste management unit is equal to or greater than 500 ppmw, then an explanation of the reason or reasons why the waste was not managed in accordance with this subpart.

(e) All records required by paragraphs (a), (b), (c) and (d) of this section except as required in paragraphs (a)(3), (a)(4), and a(5) shall be maintained in the operating record until closure of the facility. All records required by paragraph (a)(3), (a)(4), and (a)(5) of this section shall be maintained in the operating record for a minimum of three years.

(f) The owner or operator of any facility that is subject to this subpart and to the control device regulations in 40 CFR 60 subpart VV, or 40 CFR 61 subpart V, may elect to demonstrate compliance with this subpart by documentation either pursuant to this subpart, or pursuant to the provisions of 40 CFR part 60 or 61, to the extent that the documentation under 40 CFR part 60 or part 61 duplicates the documentation required under this subpart.

(Approved by the Office of Management and Budget under control number 2060-____.)

§ 264.1089 Reporting requirements.

(a) The owner or operator of a facility where a hazardous waste management unit is excepted from standards pursuant to § 264.1081(a) shall report the results of each waste determination completed in accordance with § 264.1082 (a) or (b) whenever the volatile organic concentration of the waste placed in the hazardous waste management unit is equal to or greater than 500 ppmw. The report shall be signed and dated by an authorized representative of the owner or operator, and include the EPA identification number, facility name and address, and an explanation of the reason or reasons why the waste was not managed in accordance with this subpart. The owner or operator shall submit this report to the Regional Administrator within 30 calendar days after the owner or operator has completed the determination. Failure to report shall constitute noncompliance with this subpart.

(b) The owner or operator of a facility where a tank is excepted from standards pursuant to § 264.1083(b)(2) shall report the results of each waste determination completed in accordance with § 264.1082(c) whenever the maximum organic vapor pressure of the waste placed in the tank exceeds the maximum organic vapor pressure limit for the tank's design capacity category specified in § 264.1083(b)(2)(i)(D). The report shall be signed and dated by an authorized representative of the owner or operator, and include the EPA identification number, facility name and address, and an explanation of the

reason or reasons why the waste was not managed in accordance with this subpart. The owner or operator shall submit this report to the Regional Administrator within 30 calendar days after the owner or operator has completed the determination. Failure to report shall constitute noncompliance with this subpart.

(c) The owner or operator of a facility where a control device is used to comply with §§ 264.1083, 264.1084, or 264.1085 of this subpart shall report each occurrence when a control device is operated continuously at conditions which exceed for 24 hours or longer the appropriate control device operating values defined in § 264.1035(c)(4) of this part or that a flare is operated with visible emissions as defined in § 264.1033(d). The owner or operator shall submit this report to the Regional Administrator at least once every six month period. The report shall be signed and dated by an authorized representative of the owner or operator, and include the EPA identification number, facility name and address, and an explanation why the control device could not be returned to proper operation within 24 hours.

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§ 264.1090 Alternative control requirements for tanks.

(a) The owner or operator of a hazardous waste management facility that manages waste in tanks may install and operate one of the following types of control equipment as an alternative to complying with § 264.1083(b)(1) of this subpart.

(1) A fixed roof and internal floating roof. The fixed roof shall comply with the requirements of § 264.1083(b)(1)(i)(A) of this subpart. The internal floating roof shall rest or float on the liquid surface (but not necessarily in complete contact with it) inside a tank that has a fixed roof. The internal floating roof shall be floating on the waste surface at all times, except during initial fill and during those intervals when the tank is completely emptied or subsequently emptied and refilled. When the roof is resting on the leg supports, the process of filling, emptying, or refilling shall be continuous and shall be accomplished as rapidly as possible.

(i) Each internal floating roof shall be equipped with one of the following closure devices between the wall of the tank and the edge of the internal floating roof:

(A) A foam- or liquid-filled seal mounted in contact with the liquid (liquid-mounted seal). A liquid-mounted seal means a foam- or liquid-filled seal mounted in contact with the liquid between the wall of the tank and the floating roof continuously around the circumference of the tank.

(B) Two seals mounted one above the other so that each forms a continuous closure that completely covers the space between the wall of the tank and the edge of the internal floating roof. The lower seal may be vapor-mounted, but both shall be continuous.

(C) A mechanical shoe seal. A mechanical shoe seal is a metal sheet held vertically against the wall of the tank by springs or weighted levers and is connected by braces to the floating roof. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof.

(ii) Each opening in a noncontact internal floating roof except for automatic bleeder vents (vacuum breaker vents) and the rim space vents is to provide a projection below the waste surface.

(iii) Each opening in the internal floating roof except for leg sleeves, automatic bleeder vents, rim space vents, column wells, ladder wells, sample wells, and stub drains is to be equipped with a cover or lid which is to be maintained in a closed position at all times (i.e., no visible gap) except when the device is in actual use. The cover or lid shall be equipped with a gasket. Covers on each access hatch and automatic gauge float well shall be bolted except when they are in use.

(iv) Automatic bleeder vents shall be equipped with a gasket and are to be closed at all times when the roof is floating except when the roof is being floated off or is being landed on the roof leg supports.

(v) Rim space vents shall be equipped with a gasket and are to be set to open only when the internal floating roof is not floating or at the manufacturer's recommended setting.

(vi) Each penetration of the internal floating roof for the purpose of sampling shall be a sample well. The sample well shall have a slit fabric cover that covers at least 90 percent of the opening.

(vii) Each penetration of the internal floating roof that allows for passage of a column supporting the fixed roof shall have a flexible fabric sleeve seal or a gasketed sliding cover.

(viii) Each penetration of the internal floating roof that allows for passage of a ladder shall have a gasketed sliding cover.

(2) An external floating roof. Each external floating roof shall meet the following specifications:

(i) Each external floating roof shall be equipped with a closure device between the wall of the tank and the roof edge. The closure device is to consist of two seals, one above the other. The lower seal is referred to as the primary seal, and the upper seal is referred to as the secondary seal.

(A) The primary seal shall be either a mechanical shoe seal or a liquid-mounted seal. Except as provided in § 264.1090(b)(2)(iv) of this section, the seal shall completely cover the annular space between the edge of the floating roof and tank well.

(B) The secondary seal shall completely cover the annular space between the external floating roof and the wall of the storage vessel in a continuous fashion except as allowed in § 264.1090(b)(2)(iv) of this section.

(ii) Except for automatic bleeder vents and rim space vents, each opening in a noncontact external floating roof shall provide a projection below the waste surface. Except for automatic bleeder vents, rim space vents, roof drains, and leg sleeves, each opening in the roof is to be equipped with a gasketed cover, seal, or lid that is to be maintained in a closed position at all times (i.e., no visible gap) except when the device is in actual use. Automatic bleeder vents are to be closed at all times when the roof is floating except when the roof is being floated off or is being landed on the roof leg supports. Rim vents are to be set to open when the roof is being floated off the roof leg supports or at the manufacturer's recommended setting. Automatic bleeder vents and rim space vents are to be gasketed. Each emergency roof drain is to be provided with a slotted membrane fabric cover that covers at least 90% of the area of the opening.

(iii) The roof shall be floating on the waste at all times (i.e., off the roof leg supports) except during initial fill until the roof is lifted off leg supports and when the tank is completely emptied and subsequently refilled. The process of filling, emptying, or refilling when the roof is resting on the leg supports shall be continuous and shall be accomplished as rapidly as possible.

(3) An alternative means of emission limitation for which a **Federal Register** notice has been published according to the provision of 40 CFR 60.114b permitting its use as an alternative means for purposes of compliance with 40 CFR 60.112b.

(b) Monitoring and inspection of the control equipment described in paragraphs (a)(1) and (a)(2) of this section shall be conducted as follows:

(1) After installation, owners and operators of internal floating roofs shall:

(i) Visually inspect the internal floating roof, the primary seal, and the

secondary seal (if one is in service), prior to filling the tank with waste. If there are holes, tears, or other openings in the primary seal, the secondary seal, or the seal fabric, or defects in the internal floating roof, or both, the owner or operator shall repair the items before filling the tank.

(ii) For tanks equipped with a liquid mounted or mechanical shoe primary seal, visually inspect the internal floating roof and the primary seal or the secondary seal (if one is in service) through manholes and roof hatches on the fixed roof at least once every 12 months after initial fill. If the internal floating roof is not resting on the surface of the waste inside the tank, or there is liquid accumulated on the roof, or the seal is detached, or there are holes or tears in the seal fabric, the owner or operator shall repair the items or empty and remove the tank from service within 45 days. If a failure that is detected during inspections required in this paragraph cannot be repaired within 45 days and if the tank cannot be emptied within 45 days, a 30-day extension may be requested from the Regional Administrator in the inspection report required in § 264.1090(c)(1)(ii) of this section. Such a request for an extension shall document that alternate capacity is unavailable and specify a schedule of actions the company will take that will assure that the control equipment will be repaired or the tank will be emptied as soon as possible.

(iii) For tanks equipped with a double-seal system as specified in § 264.1090(a)(1)(i)(B) of this section:

(A) Visually inspect the tank as specified in paragraph (b)(1)(iv) of this section at least every 5 years; or

(B) Visually inspect the tank as specified in paragraph (b)(1)(ii) of this section.

(iv) Visually inspect the internal floating roof, the primary seal, the secondary seal (if one is in service), gaskets, slotted membranes (if any), and sleeve seals (if any) each time the tank is emptied and degassed. If the internal floating roof has defects, the primary seal has holes, tears, or other openings in the seal or the seal fabric, or the gaskets no longer close off the liquid surfaces from the atmosphere, or the slotted membrane has more than 10 percent open area, the owner or operator shall repair the items as necessary so that none of the conditions specified in this paragraph exist before refilling the tank with waste. In no event shall inspections conducted in accordance with this provision occur at intervals greater than 10 years in the case of tanks conducting the annual visual inspection as specified in paragraph (b)(1)(ii) of this section, and at intervals no greater than 5 years in the case of tanks specified in paragraph (b)(1)(iii) of this section.

(v) Notify the Regional Administrator in writing at least 30 days prior to the filling or refilling of each tank for which an inspection is required by paragraphs (b)(1)(i) and (b)(1)(iv) of this section to afford the Regional Administrator the opportunity to have an observer present. If the inspection required by paragraph (b)(1)(iv) of this section is not planned and the owner or operator could not have known about the inspection 30 days in advance of refilling the tank, the owner or operator shall notify the Regional Administrator at least 7 days prior to the refilling of the tank. Notification shall be made by telephone immediately followed by written documentation demonstrating why the inspection was unplanned. Alternatively, this notification, including the written documentation, may be made in writing and sent by express mail so that it is received by the Regional Administrator at least 7 days prior to the refilling.

(2) After installation, owners and operators of external floating roofs shall:

(i) Determine the gap areas and maximum gap widths between the primary seal and the wall of the tank and between the secondary seal and the wall of the tank according to the following frequency.

(A) Measurements of gaps between the tank wall and the primary seal (seal gaps) shall be performed during the hydrostatic testing of the tank or within 60 days of the initial fill with waste and at least once every 5 years thereafter.

(B) Measurements of gaps between the tank wall and the secondary seal shall be performed within 60 days of the initial fill with waste and at least once per year thereafter.

(C) If any tank ceases to hold waste for a period of 1 year or more, subsequent introduction of waste into the tank shall be considered an initial fill for the purposes of paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section.

(ii) Determine the gap widths and areas in the primary and secondary seals individually by the following procedures:

(A) Measure seal gaps, if any, at one or more floating roof levels when the roof is floating off the roof leg supports.

(B) Measure seal gaps around the entire circumference of the tank in each place where a 0.32 cm (0.13 in) diameter uniform probe passes freely (without forcing or binding against the seal) between the seal and the wall of the tank and measure the circumferential distance of each such location.

(C) The total surface area of each gap described in paragraph (b)(2)(ii)(B) of this section shall be determined by using probes of various widths to measure accurately the actual distance from the tank wall to the seal and multiplying each such width by its respective circumferential distance.

(iii) Add the gap surface area of each gap location for the primary seal and the secondary seal individually and divide the sum for each seal by the nominal diameter of the tank and compare each ratio to the respective standards in paragraph (b)(2)(iv) of this section.

(iv) Make necessary repairs or empty the tank within 45 days of identification in any inspection for seals not meeting the following requirements:

(A) The accumulated area of gaps between the tank wall and the mechanical shoe or liquid-mounted primary seal shall not exceed 212 cm^2 per meter (10.1 in^2 per foot) of tank diameter, and the width of any portion of any gap shall not exceed 3.81 cm (1.5 in).

(*1*) One end of the mechanical shoe is to extend into the stored waste, and the other end is to extend a minimum vertical distance of 61 cm (24.0 in) above the stored waste surface.

(*2*) There are to be no holes, tears, or other openings in the shoe, seal fabric, or seal envelope.

(B) The secondary seal is to meet the following requirements:

(*1*) The secondary seal is to be installed above the primary seal so that it completely covers the space between the roof edge and the tank wall except as provided in paragraph (b)(2)(ii)(C) of this section.

(*2*) The accumulated area of gaps between the tank wall and the secondary seal shall not exceed 21.2 cm^2 per meter (1.01 in^2 per foot) of tank diameter, and the width of any portion of any gap shall not exceed 1.27 cm (0.50 in).

(*3*) There are to be no holes, tears, or other openings in the seal or seal fabric.

(v) If a failure that is detected during inspections required in paragraph (b)(2)(i) of this section cannot be repaired within 45 days and if the tank cannot be emptied within 45 days, a 30-day extension may be requested from the Regional Administrator in the inspection report required in § 264.1090(c)(2)(iii) of this section. Such extension request shall include a demonstration of the unavailability of alternate storage capacity and a specification of a schedule that will assure that the control equipment will

be repaired or the tank will be emptied as soon as possible.

(vi) Notify the Regional Administrator 30 days in advance of any gap measurements required by paragraph (b)(2)(i) of this section to afford the Regional Administrator the opportunity to have an observer present.

(vii) Visually inspect the external floating roof, the primary seal, secondary seal, and fittings each time the vessel is emptied and degassed.

(A) If the external floating roof has defects, the primary seal has holes, tears, or other openings in the seal or the seal fabric, or the secondary seal has holes, tears, or other openings in the seal or the seal fabric, the owner or operator shall repair the items as necessary so that none of the conditions specified in this paragraph exist before filling or refilling the tank with waste.

(B) For all the inspections required by paragraph (b)(2)(vii) of this section, the owner or operator shall notify the Regional Administrator in writing at least 30 days prior to the filling or refilling of each tank to afford the Regional Administrator the opportunity to inspect the tank prior to refilling. If the inspection required by paragraph (b)(2)(vii) of this section is not planned and the owner or operator could not have known about the inspection 30 days in advance of refilling the tank, the owner or operator shall notify the Regional Administrator at least 7 days prior to the refilling of the tank. Notification shall be made by telephone immediately followed by written documentation demonstrating why the inspection was unplanned. Alternatively, this notification, including the written documentation, may be made in writing and sent by express mail so that it is received by the Regional Administrator at least 7 days prior to the refilling.

(c) Owners and operators who elect and operate the control equipment in paragraph (a) of this section shall include the following information in the operating record:

(1) *Internal floating roof.* (i) Documentation that describes the control equipment design and certifies that the control equipment meets the specifications of § 264.1090 (a)(1) and (b)(1) of this section.

(ii) Records of each inspection performed as required by § 264.1090(b)(1) (i)–(iv) of this section. Each record shall identify the tank on which the inspection was performed and shall contain the date the tank was inspected and the observed condition of each component of the control equipment (seals, internal floating roof, and fittings).

(ii) If any of the conditions described in § 264.1090(b)(1)(ii) of this section are detected during the annual visual inspection required by § 264.1090(b)(1)(ii) of this section, the records shall identify the tank, the nature of the defects, and the date the tank was emptied or the nature of and date the repair was made.

(iii) After each inspection required by § 264.1090(b)(1)(iii) of this section that finds holes or tears in the seal or seal fabric, or defects in the internal floating roof, or other control equipment defects listed in § 264.1090(b)(1)(ii) of this section, the records shall identify the tank and the reason it did not meet the specifications of § 264.1090(a)(1) or § 264.1090(b)(1)(iii) of this section and describe each repair made.

(2) *External floating roof.* (i) Documentation that describes the control equipment design and certifies that the control equipment meets the specifications of § 264.1090(a)(2) and § 264.1090(b)(2) (ii)–(iv) of this section.

(ii) Records of each gap measurement performed as required by § 264.1090(b)(2) of this section. Each record shall identify the tank in which the measurement was performed, the date of measurement, the raw data obtained in the measurement, and the calculations described in § 264.1090(b)(2)(ii) and (b)(2)(iii) of this section.

(iii) Records for each seal gap measurement that detects gaps exceeding the limitations specified by § 264.1090(b)(2)(iv) of this section that identifies the tank, the date the tank was emptied or the repairs made, and the nature of the repair.

18. In 40 CFR part 264, appendix X is added to read as follows:

Appendix X to Part 264—Calculation Procedure for Determination of Waste Volatile Organic Concentration

Appendix X describes the calculation procedure that shall be used to compute the waste volatile organic concentration value for comparison to the limit specified in § 264.1081(a)(1) of this part. Any inferences derived from the value determined by the procedure described in this appendix apply only to those times at which sampling is performed. The procedure makes no attempt to draw inferences to any other times; however, the requirement to sample when the waste volatile organic concentration is expected to be highest suggests that waste concentrations at other times should not exceed the value determined by the procedure.

The mean of the logarithms of the sample measurements is calculated and a t-test is performed to determine whether the waste volatile organic concentration is less than 500 ppmw.

Notation

n_i = number of waste samples selected at the i^{th} time period (for any sampling period, n_1 shall be at least 4).

X_{ij} = natural logarithm of the measured volatile organic concentration of the j^{th} sample at time i (i=0,1,2,..., and j=1,2,...,n_i);

$\bar{X}_i$ = the mean of the X_{ij} at time period i.

$$\bar{X}_i = \sum_j X_{ij}/n_i \qquad \text{(Eq. 1)}$$

s_i = the standard deviation of the X_{ij} at time period i.

$$s_i = \sqrt{\frac{\sum_j X_{ij}^2 - \left(\sum_j X_{ij}\right)^2/n_i}{n_i - 1}}$$

(Eq. 2)

K_i = degrees of freedom used in t-test at time i:

$$K_i = (n_i - 1) \qquad \text{(Eq. 3)}$$

A t-test is used to determine if the waste volatile organic concentration is below the action level, 500 ppmw. The null hypothesis is that the true geometric mean of samples taken at time i is 500 ppmw (or more); the alternative hypothesis is that it is less than 500 ppmw. The test is conducted at the 0.10 significance level. Critical values of the t-distribution with K_i degrees of freedom (the upper 90th percentage point) are given in Column 2 of Table X.1 and are denoted below as t_i. The null hypothesis for time i is rejected (i.e., the waste is judged to qualify for management in units that are not controlled for organic air emissions) if:

$$\frac{\bar{X}_i - \ln(500)}{s_i/\sqrt{n_i}} < -t_i, \qquad \text{(Eq. 4)}$$

Or equivalently, if:

$$\exp(\bar{X}_i + t_i\, s_i/\sqrt{n_i}) < 500 \qquad \text{(Eq. 5)}$$

For waste determinations, X_i is calculated by averaging the logarithms of the measured values using Equation 1. The other values for the t-test, s_i and K_i, are calculated from Equations 2 and 3, respectively.

TABLE X.1. PERCENTAGE POINTS OF t-DISTRIBUTIONS

Degrees of Freedom, K_i	90-th percentage point, t_i
1	3.078
2	1.886

TABLE X.1. PERCENTAGE POINTS OF t-DISTRIBUTIONS—Continued

Degrees of Freedom, K_i	90-th percentage point, t_i
3	1.638
4	1.533
5	1.476
6	1.440
7	1.415
8	1.397
9	1.383
10	1.372
11	1.363
12	1.356
13	1.350
14	1.345
15	1.341
16	1.337
17	1.333
18	1.330
19	1.328
20	1.325
21	1.323
22	1.321
23	1.319
24	1.318
25	1.316
26	1.315
27	1.314
28 and over	1.313

19. In 40 CFR part 264, appendix XI is added to read as follows:

Appendix XI to Part 264—Calculation Procedure for Weighted Average Waste Volatile Organic Concentratio

Appendix XI describes the calculation procedure that shall be used to compute the weighted average waste volatile organic concentration value for determining if waste dilution has occurred per § 264.1082(b)(2) of this part. The equation is used to calculate the weighted average volatile organic concentration for all of the waste streams entering the treatment unit. For a waste stream entering the treatment unit having a volatile organic concentration equal to or greater than 500 ppmw, the measured concentration is used in the equation. For a waste stream entering the treatment unit having a volatile organic concentration less than 500 ppmw, the value of 500 ppmw is used in the equation.

$$C = \frac{\sum_{j=1}^{m}(Q_{aj} \times 500\ ppmw) + \sum_{i=1}^{n}(Q_{bi} \times C_{bi})}{\sum_{j=1}^{m} Q_{aj} + \sum_{i=1}^{n} Q_{bi}}$$

(Eq. 6)

where:

C = volatile organic concentration (ppm by weight)

Q_{aj} = quantity of each waste stream (j) to be treated that has a volatile organic concentration greater than or equal to 500 ppmw (Mg), concentration as measured at the point described in § 264.1082(a)(1)

Q_{bi} = quantity of each waste stream (i) to be treated that has a volatile organic concentration less than 500 ppmw (Mg)

C_{bi} = the concentration of each waste stream (i) to be treated that is less than 500 ppmw (ppmw), as measured at the point described in § 264.1082(a)(1)

m = the number of waste streams with concentration greater than or equal to 500 ppmw

n = the number of waste streams with concentration less than 500 ppmw.

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

20. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6935.

Subpart A—General

§ 265.1 [Amended]

21–23. Section 265.1(b) is amended by adding the phrase "Except as provided in § 265.1080(b)," before the phrase "The standards of this part apply to * * *"

Subpart B—General Facility Standards

§ 265.13 [Amended]

24. In § 265.13, paragraph (b)(6) is amended by adding "265.1083," after the phrase "as specified in §§ 265.200. 265.225, 265.252, 265.273, 265.314, 265.341, 265.375, 265.402, 265.1034(d), 265.1063(d),".

25. In § 265.13, paragraph (b)(8) is added to read as follows:

§ 265.13 General waste analysis.

* * * * *

(b) * * *

(8) For owners and operators seeking an exception to the air emission standards of subpart CC in accordance with § 265.1082—

(i) The procedures and schedules for waste sampling and analysis, and the analysis of test data to verify the exception.

(ii) Each generator's notice and certification of the volatile organic concentration in the waste if the waste is received from offsite.

* * * * *

§ 265.15 [Amended]

26. In § 265.15, paragraph (b)(4) is amended by removing the word "and" after the phrase "frequenciescalled for in §§ 265.174, 265.193, 265.195, 265.226, 265.347, 265.377, 265.403, 265.1033, 265.1052, 265.1053," and inserting "265.1087, 265.1088, and 265.1090(b)," after "265.1058,".

Subpart E—Manifest System, Recordkeeping, and Reporting

27. Section 265.73 is amended by revising paragraphs (b)(3) and (b)(6) to read as follows:

§ 265.73 Operating record.

* * * * *

(b) * * *

(3) Records and results of waste analysis and trial tests performed as specified in §§ 265.13, 265.193, 265.225, 265.252, 265.273, 265.314, 265.341, 265.375, 265.402, 265.1034, 265.1063, 265.1083, 268.4(a), and 268.7 of this chapter.

* * * * *

(6) Monitoring, testing or analytical data when required by §§ 265.90, 265.94, 265.191, 265.193, 265.195, 265.276, 265.278, 265.280(d)(1) , 265.347, 265.377, 265.1034(c)–(f), 265.1035, 265.1063(d)–(i), 265.1064, 265.1089, and 265.1090(b).

* * * * *

28. In Section 265.77, paragraph (d) is revised to read as follows:

§ 265.77 Additional reports.

* * * * *

(d) As otherwise required by subparts AA, BB, and CC.

Subpart I—Use and Management of Containers

29. Section 265.178 is added to read as follows:

§ 265.178 Air emission standards.

Containers shall be managed in compliance with the air emission standards in subparts AA, BB, and CC of this part.

Subpart J—Tank Systems

30. Section 265.202 is added to read as follows:

§ 265.202 Air emission standards.

Tanks shall be managed in compliance with the air emission standards in subparts AA, BB, and CC of this part.

Subpart K—Surface Impoundments

31. Section 265.231 is added to read as follows:

§ 265.231 Air emission standards.

Surface impoundments shall be managed in compliance with the air emission standards in subparts AA, BB, and CC of this part.

Subpart AA—Air Emission Standards for Process Vents

32. Section 265.1033 is amended by adding paragraph (l) to read as follows:

§ 265.1033 Standards: Closed-vent systems and control devices.

* * * * *

(l) The owner or operator using a carbon adsorption system shall certify that all carbon removed from a carbon adsorption system to comply with § 265.1033 (g)–(h) of this part is either:

(1) Regenerated or reactivated by a process that minimizes emissions of organics to the atmosphere. (Note: EPA interprets "minimizes" as used in this paragraph to include the application of effective control devices such as those required in this subpart); or

(2) Incinerated by a process that achieves the performance standards specified in subpart O of part 264 of this title.

33. In 40 CFR part 265, subpart CC is added to read as follows:

Subpart CC—Air Emission Standards for Tanks, Surface Impoundments, and Containers

Sec.

Subpart CC—Air Emission Standards for Tanks, Surface Impoundments, and Containers

§ 265.1080 Applicability.

(a) The regulations in this subpart apply to owners and operators of facilities that treat, store, or dispose of hazardous waste in units that are subject to subparts I, J, and K of this part except as provided in § 265.1 of this part.

(b) The regulations in this subpart apply to owners and operators of facilities that treat, store, or dispose of hazardous waste in units that are subject to subparts I, J, and K of part 265 who received a final permit under section 3005 of RCRA prior to the effective date of this rule (6 months after the promulgation date of the final rule) until permit reissue or review.

§ 265.1081 Schedule for implementation of air emission standards.

(a) Owners or operators of all hazardous waste facilities existing on the date when the final rule is published in the **Federal Register** and subject to subparts I, J, and K of this part.

(1) Owners or operators shall, where applicable, install and operate control equipment as provided in §§ 265.1084 through 265.1087 by the effective date of the final rule (6 months after promulgation in the **Federal Register**).

(2) When control equipment is required and cannot be installed and operating by the effective date, the owner or operator must—

(i) Install and operate the control equipment as soon as possible but no later than 2 years after the date on which the final rule is promulgated in the **Federal Register**, and

(ii) For facilities subject to the recordkeeping requirements of § 265.73, enter and maintain an implementation schedule in the operating record on the effective date of the final rule.

(iii) For facilities not subject to § 265.73, the owner or operator shall enter, by the effective date of the final rule, and maintain an implementation schedule in a permanent, readily available file located at the plant site.

(b) Owners or operators of facilities in existence on the effective date of statutory or regulatory amendments under the Act that render the facility subject to subparts I, J, and K of this part.

(1) Owners or operators shall, where applicable, install and operate control equipment as provided in § 265.1084 through 265.1087 by the effective date of the amendment.

(2) When control equipment is required and cannot be installed and operating by the effective date of the amendment, the owner or operator shall—

(i) Install and operate the control equipment as soon as possible but no later than 18 months after the effective date, and

(ii) For facilities subject to the recordkeeping requirements of § 265.73, enter and maintain an implementation schedule in the operating record on the effective date of the final rule.

(iii) For facilities not subject to § 265.73, the owner or operator shall enter, by the effective date of the final rule, and maintain an implementation schedule in a permanent, readily available file located at the plant site.

§ 265.1082 Exceptions to the standards.

(a) A hazardous waste management unit is excepted from standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart provided that the owner or operator meets all of the following requirements:

(1) Determines in accordance with the procedures specified in § 265.1083 of this subpart that the waste placed in the hazardous waste management unit at all times has a volatile organic concentration less than 500 parts per million by weight (ppmw) at either:

(i) A point before the waste is first exposed to the atmosphere such as in an enclosed pipe or other closed system that is used to transfer the waste after generation to the first hazardous waste management unit; or

(ii) The outlet of a treatment unit that:

(A) Removes or destroys organics in the waste using a means other than by waste dilution or evaporation into the atmosphere; and

(B) Is in compliance with all applicable standards in this part.

(2) Performs the waste determination required by paragraph (a)(1) of this section at least once per year and whenever the process, operation, or source generating the waste changes in such a manner that the volatile organic concentration of the waste may change.

(b) An owner or operator may place waste in a hazardous waste management unit without the control equipment specified in §§ 265.1084, 265.1085, and 265.1086 of this subpart provided that the owner or operator provides documentation certifying that the waste placed in the hazardous waste management unit complies with the applicable treatment standards for organic-containing waste pursuant to the requirements of subpart D in part 268 of this title.

§ 265.1083 Waste determinations.

(a) Waste volatile organic concentration determination for an exception under § 265.1082(a)(1)(i) of this subpart.

(1) The owner or operator shall use either direct measurement, knowledge of the waste, or waste certification to determine the volatile organic concentration of the waste in accordance with the following requirements:

(i) *Direct measurement.* (A) All waste samples shall be collected at a point before the waste is first exposed to the atmosphere and at a time when the maximum volatile organic concentration in the waste stream is expected to occur. The sampling program shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW–846.

(B) A minimum of four representative samples shall be collected and analyzed using the test procedures specified in Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846; and the calculation procedure specified in Appendix VI of this part.

(C) If the waste volatile organic concentration determined in paragraph (a)(1)(i)(B) of this section is less than 500 ppmw then the waste may be placed in a hazardous waste management unit pursuant to § 265.1082(a) of this subpart.

(ii) *Knowledge of the waste.* The owner or operator shall provide sufficient information to document that the volatile organic concentration of the waste at all times is less than 500 ppmw. Examples of information that may be used include documentation that the waste is generated by a process for which no organics-containing materials are used, or the waste is generated by a process for which it previously has been determined by direct measurement at other locations using the same type of process that the waste has a volatile organic concentration less than 500 ppmw.

(iii) *Waste Certification.* If an owner or operator cannot perform the waste determination at a point before the waste is first exposed to the atmosphere because the waste is generated off site, then the owner or operator may determine the waste volatile organic concentration upon receiving the waste from the generator provided the waste is accompanied by:

(A) A notice that includes the following information:

(*1*) EPA Hazardous Waste Number,

(*2*) Manifest number associated with the shipment of hazardous waste, and

(*3*) Volatile organic concentration waste determination results obtained in accordance with the methods specified in paragraph (a)(1)(i) or (a)(1)(ii) of this section.

(B) Certification that is signed and dated by an authorized representative of the generator and states the following:

I certify under penalty of law that I personally have examined and am familiar with the waste through analysis and testing or through knowledge of the waste, and I support this certification that the waste does not exceed a volatile organic concentration of 500 ppmw. I believe that the information submitted is true, accurate, and complete. I am aware that there are significant penalties for submitting a false certification, including the possibility of a fine and imprisonment.

(2) The Regional Administrator may request at any time that the owner or operator perform a waste determination in accordance with paragraph (a)(1)(i) of this section. A result from the waste determination requested by the Regional Administrator indicating that the waste volatile organic concentration is equal to or greater than 500 ppmw shall be conclusive evidence that each hazardous waste management unit in which the waste has been placed is not excepted from standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart.

(b) Waste determination of volatile organic concentration for an exception under § 265.1082(a)(1)(ii) of this subpart.

(1) The owner or operator shall use either direct measurement or knowledge of the waste to determine the volatile organic concentration of the waste at the outlet of the treatment unit and whether waste dilution was used to achieve this concentration in accordance with the following requirements:

(i) *Direct measurement.* (A) Determination of the volatile organic concentration of the waste at the outlet from the treatment unit.

(*1*) All waste samples shall be collected at the treatment unit outlet and at a time when the maximum volatile organic concentration in the waste stream is expected to occur. The sampling program shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846.

(*2*) A minimum of four representative samples shall be collected and analyzed using the test procedures specified in Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846; and the calculation procedure specified in appendix VI of this part.

(B) Determination that no waste dilution has occurred.

(*1*) Representative waste samples for each waste stream entering and exiting the treatment unit shall be collected as near in time as possible. The sampling program shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846.

(*2*) The samples shall be analyzed using the test procedures specified in Reference Method 25D in 40 CFR part 60 appendix A or Test Method 5100 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846 to determine the volatile organic concentration of each waste stream entering and exiting the treatment unit. A weighted average volatile organic concentration for all of the waste streams entering the treatment unit shall be calculated using the procedure specified in appendix VII of this part.

(*3*) If the weighted average volatile organic concentration for all streams entering the treatment unit is greater than the volatile organic concentration for the waste stream exiting the treatment unit as determined in accordance with paragraph (b)(1)(i)(B)(*2*) of this section, then no waste dilution has occurred.

(C) If the waste volatile organic concentration at the outlet of the treatment unit as determined in paragraph (b)(1)(i)(A) of this section is less than 500 ppmw and no waste dilution has occurred as determined in paragraph (b)(1)(i)(B), of this section, then the waste may be placed in a hazardous waste management unit in accordance with § 265.1082(a) of this subpart.

(ii) *Knowledge of the waste.* The owner or operator shall provide sufficient information to document that the volatile organic concentration of the waste exiting the treatment unit is less than 500 ppmw at all times and that no waste dilution has occurred.

(2) The Regional Administrator may request at any time that the owner or operator perform a waste determination in accordance with paragraph (b)(1)(i) of this section. A result from the waste determination requested by the Regional Administrator indicating that the waste volatile organic concentration is equal to or greater than 500 ppmw or that waste dilution has occurred shall be conclusive evidence that each hazardous waste management unit in which the waste has been placed is not excepted from standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart.

(c) Waste determination of maximum organic vapor pressure for a tank having a design capacity equal to or greater than 75 m^3 in accordance with § 265.1084(b)(2) of this subpart.

(1) The owner or operator shall use either direct measurement or knowledge of the waste to determine the maximum organic vapor pressure of the waste in accordance with the following requirements:

(i) *Direct measurement.* (A) All waste samples shall be collected at the inlet to the tank. Sampling shall be conducted in accordance with the requirements specified in "Test Methods for Evaluating Solid Waste, Physical/

Chemical Methods," EPA Publication No. SW-846.

(B) Any one of the following methods may be used to analyze the samples and compute the maximum organic vapor pressure:

(*1*) Reference Method 25E in 40 CFR part 60 appendix A or Test Method 5110 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication No. SW-846;

(*2*) Methods described in American Petroleum Institute Bulletin 2517, 'Evaporation Loss From External Floating Roof Tanks," (incorporated by reference—refer to § 260.11);

(*3*) Methods obtained from standard reference texts;

(*4*) ASTM Method 2879-83 (incorporated by reference—refer to § 260.11); or

(*5*) Any other method approved by the Regional Administrator.

(ii) *Knowledge of the waste.* The owner or operator shall provide sufficient information to document that the maximum organic vapor pressure at all times is less than the maximum vapor pressure limit for the appropriate tank design capacity category specified in § 265.1084(b)(2)(i)(D). Examples of information that may be used include documentation that the waste is generated by a process for which no organics-containing materials are used, or the waste is generated by a process for which at other locations it previously has been determined by direct measurement that the waste maximum organic vapor pressure is less than the maximum vapor pressure limit for the appropriate tank design capacity category specified in § 265.1084(b)(2)(i)(D).

(2) The Regional Administrator may request at any time that the owner or operator perform a waste determination in accordance with paragraph (c)(1)(i) of this section. A result from the waste determination requested by the Regional Administrator indicating that the waste maximum organic vapor pressure exceeds the appropriate maximum organic vapor pressure limit for the appropriate tank design capacity category specified in § 265.1084(b)(2)(i)(D) shall be conclusive evidence that each tank in which the waste has been placed is not excepted from requirements pursuant to § 265.1084(b)(1) of this subpart.

§ 265.1084 Standards: tanks.

(a) *Applicability.* This section applies to the owner or operator of a facility where hazardous waste is placed in tanks except as provided in § 265.1082 of this subpart.

(b) *Design and operation of control equipment.* (1) The owner or operator shall meet one of the following control equipment requirements except as provided in paragraph (b)(2) of this section:

(i) Install, operate, and maintain a fixed roof cover and closed vent system that routes the organic vapors vented from the tank to a control device.

(A) The fixed roof shall meet the following requirements:

(*1*) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(*2*) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the tank except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(B) The closed vent system and control device shall be designed and operated in accordance with the requirements of § 265.1087 of this subpart.

(ii) Install, operate, and maintain a pressurized tank that is designed to operate at a pressure in excess of 204.9 kPa (29.7 psi) and that operates with no detectable organic emissions.

(iii) Install, operate, and maintain alternative control equipment in accordance with the requirements of § 265.1090 of this subpart.

(2) As an alternative to the control equipment specified in paragraph (b)(1) of this section, an owner or operator may install, operate, and maintain on a tank that meets all of the conditions specified in paragraph (b)(2)(i) of this section a fixed roof as specified in paragraph (b)(2)(ii) of this section.

(i) The waste placed in the tank shall meet the following conditions:

(A) The waste is quiescent at all times that the waste is managed in the tank;

(B) The waste is not managed in the tank using a waste fixation process;

(C) The waste is not managed in the tank using a process that requires the addition of heat to the waste or produces an exothermic reaction: and

(D) The waste is either:

(*1*) Placed in a tank having a design capacity less than 75 m^3 (19,789 gal);

(*2*) Placed in a tank having a design capacity greater than or equal to 75 m^3 (19,789 gal) but less than 151 m^3 (39,841 gal), and the waste has a maximum organic vapor pressure less than 27.6 kPa (4.0 psi); or

(*3*) Placed in a tank having a design capacity greater than or equal to 151 m^3 (39,841 gal), and the waste has a maximum organic vapor pressure less than 5.2 kPa (0.75 psi).

(ii) The fixed roof shall meet the following requirements:

(A) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed to operate with no detectable organic emissions.

(B) Each cover vent that discharges to the atmosphere shall be equipped with a pressure-relief valve, a pressure-vacuum valve, a pilot-operated relief valve, or equivalent pressure-relief device. The device shall be operated so that no detectable organic emissions occur from the vent except during periods when conditions such as filling or emptying the tank or diurnal temperature changes require venting of the tank to prevent physical damage or permanent deformation of the tank or cover.

(C) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the tank except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(3) No waste shall be placed in the tank whenever control equipment specified in paragraphs (b)(1) or (b)(2) of this section is not in operation.

(c) The owner and operator shall install, operate, and maintain enclosed pipes or other closed systems to:

(1) Transfer waste to the tank from all other hazardous waste management units subject to standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart, and

(2) Transfer waste from the tank to all other hazardous waste management units subject to standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart.

§ 265.1085 Standards: surface impoundments.

(a) *Applicability.* This section applies to the owner or operator of a facility where hazardous waste is placed in surface impoundments, except as provided in § 265.1082 of this subpart.

(b) *Design and operation of control equipment.* (1) The owner or operator shall install, operate, and maintain on each surface impoundment a cover (e.g., air-supported structure, rigid cover) and closed vent system that routes all organic vapors vented from the surface impoundment to a control device except as provided in paragraph (b)(2) of this section:

(i) The cover shall meet the following requirements:

(A) The cover and all cover openings (e.g., access hatches, sampling ports,

and gauge wells) shall be designed and operated with no detectable organic emissions.

(B) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the surface impoundment except when it is necessary to use the opening for waste loading, removal, inspection, or sampling, or for equipment inspection, maintenance, or repair.

(ii) The closed vent system and control device shall be designed and operated in accordance with § 265.1087 of this subpart.

(2) As an alternative to the control equipment specified in paragraph (b)(1) of this section, an owner or operator may install, operate, and maintain on a surface impoundment that meets all of the conditions specified in paragraph (b)(2)(i) of this section either a floating membrane cover as specified in paragraph (b)(2)(ii) of this section or a cover as specified in paragraph (b)(2)(iii) of this section.

(i) The waste placed in the surface impoundment shall meet the following conditions:

(A) The waste is quiescent at all times that the waste is managed in the surface impoundment;

(B) The waste is not managed in the surface impoundment using a waste fixation process;

(C) The waste is not managed in the surface impoundment using a process that requires the addition of heat to the waste or produces an exothermic reaction.

(ii) The floating membrane cover shall meet the following requirements:

(A) Be designed, constructed, and installed so that when the surface impoundment is filled to capacity, the waste surface area is covered completely;

(B) The floating membrane cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed and operated with no detectable organic emissions.

(C) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times waste is in the surface impoundment except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(D) The synthetic membrane material used for the floating membrane cover shall be either:

(*1*) High density polyethylene with a thickness no less than 2.5 mm (100 mils), or

(*2*) A material or a composite of different materials determined to have all of the following:

(*i*) Organic permeability properties that are equivalent to those of the material specified in paragraph (b)(2)(ii)(D)(*1*) of this section, and

(*ii*) Chemical and physical properties that maintain the material integrity for as long as the cover is in use. Factors that shall be considered in selecting the material include: the effects of contact with the waste managed in the impoundment, weather exposure, and cover installation and operation practices.

(iii) The cover shall meet the following requirements:

(A) The cover and all cover openings (e.g., access hatches, sampling ports, and gauge wells) shall be designed and operated with no detectable organic emissions.

(B) The waste surface shall be completely enclosed by the cover and the air space underneath the cover shall not be vented to the atmosphere.

(3) No waste shall be placed in the surface impoundment whenever control equipment specified in paragraphs (b)(1) or (b)(2) of this section is not in operation.

(c) The cover shall be used at all times that any waste is placed in the surface impoundment except during removal of treatment residues in accordance with § 268.4 of this title, or closure of the surface impoundment in accordance with § 265.228 of this part.

(d) The owner or operator shall install, operate, and maintain enclosed pipes or other closed systems to:

(1) Transfer waste to the surface impoundment from all other hazardous waste management units subject to standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart, and

(2) Transfer waste from the surface impoundment to all other hazardous waste management units subject to standards pursuant to §§ 265.1084, 265.1085, and 265.1086 of this subpart.

§ 265.1086 Standards: containers.

(a) *Applicability.* This section applies to the owner or operator of a facility where hazardous waste is placed in containers except as provided in § 265.1082 of this subpart.

(b) *Design and operation of control equipment.* (1) The owner or operator shall install, operate, and maintain a cover on each container used to handle, transfer, or store waste in accordance with the following requirements:

(i) The cover and all cover openings (e.g., bungs, hatches, and sampling ports) shall be designed to operate with no detectable organic emissions.

(ii) Each cover opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the container except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(2) Treatment of a waste in a container by either waste fixation, a process that requires the addition of heat to the waste, or a process that produces an exothermic reaction shall be performed by the owner or operator in a manner such that during the treatment process whenever it is necessary for the container to be open, the container is located under a cover (e.g., hood, enclosure) with a closed vent system that routes all organic vapors vented from the container to a control device.

(i) The cover and all cover openings (e.g., doors, hatches) shall be designed to operate with no detectable organic emissions.

(ii) The closed vent system and control device shall be designed and operated in accordance with § 265.1087 of this subpart.

(3) The owner or operator shall load pumpable waste into a container using a submerged fill pipe placed so that the outlet extends to within two fill pipe diameters of the bottom of the container while the container is being loaded. During loading of the waste, the cover shall remain in place and all cover openings shall be maintained in a closed, sealed position except for those cover openings required for the submerged fill pipe and for venting of the container to prevent physical damage or permanent deformation of the container or cover.

§ 265.1087 Standards: closed vent systems and control devices.

(a) *Applicability.* This section applies to the owner or operator of a facility where a closed vent system and control device is used to comply with standards pursuant to §§ 265.1084, 265.1085, or 265.1086 of this subpart.

(b) The owner or operator shall properly design, install, operate, and maintain each closed vent system and control device in accordance with the following requirements:

(1) The closed vent system shall operate with no detectable organic emissions at all times that any waste is in the hazardous waste management unit being controlled.

(2) The control device shall operate at the conditions that reduce the organics

in the gas stream vented to it by at least 95 percent by weight or at the conditions specified in § 265.1033 (c) and (d) of this part at all times that any waste is in the hazardous waste management unit being controlled.

(c) The owner or operator shall determine that each control device achieves the appropriate conditions specified in paragraph (b)(2) of this section in accordance with the following requirements:

(1) The owner or operator of a control device other than a flare or carbon adsorption system shall use one of the following methods:

(i) Engineering calculations in accordance with requirements specified in § 265.1035(b)(4)(iii) of this part; or

(ii) Performance tests performed using the test methods and procedures in accordance with requirements specified in § 265.1034 (c)(1)–(c)(4) of this part.

(2) The owner or operator of a flare shall use the method specified in § 265.1033(e) of this part.

(3) The owner or operator of a carbon adsorption system shall use either one of the methods specified in paragraph (c)(1)(i) or (c)(1)(ii) of this section based on the total quantity of organics vented to the atmosphere from all carbon adsorption system equipment that is used for organic adsorption, organic desorption or carbon regeneration, organic recovery, and carbon disposal.

(d) If the owner or operator and the Regional Administrator do not agree on a determination using engineering calculations of a control device organic emission reduction or, for external combustion devices, organic compound concentrations, then the disagreement shall be resolved based on the results of performance tests performed by the owner or operator using the test methods and procedures as required in § 265.1034 (c)(1)–(c)(4) of this part. The Regional Administrator may elect to have an authorized representative observe the performance tests.

(e) The owner or operator using a carbon adsorption system shall certify that all carbon removed from a carbon adsorption system to comply with § 265.1033 (g) and (h) of this part is either:

(1) Regenerated or reactivated by a process that minimizes emissions of organics to the atmosphere. (Note: EPA interprets "minimizes" as used in this paragraph to include the application of effective control devices such as those required in this subpart); or

(2) Incinerated by a process that achieves the performance standards specified in subpart O of part 264 of this title.

§ 265.1089 Monitoring and inspection requirements.

(a) *Applicability.* This section applies to the owner or operator of a facility where control equipment is used pursuant to §§ 265.1084, 265.1085, or 265.1086 of this subpart.

(b) The owner or operator shall monitor and inspect each cover, except for internal floating roofs and external floating roofs complying with § 265.1090, in accordance with the following requirements:

(1) The owner or operator shall visually inspect each cover initially upon installation of the cover and thereafter at least once per week. The visual inspection shall include inspection of fabric and sealing material on all openings for evidence of visible defects such as rips, gaps, or tears. If visible defects are observed during an inspection, then a leak is detected and the leak shall be repaired in accordance with paragraph (b)(3) of this section.

(2) The owner or operator shall monitor each cover in the following manner:

(i) Each cover connection and seal shall be monitored initially upon installation of the cover and thereafter at least once every six months in accordance with Reference Method 21 in 40 CFR part 60 appendix A.

(ii) If the monitoring instrument indicates detectable emissions (i.e., a concentration above 500 ppmv), then a leak is detected and the leak shall be repaired in accordance with paragraph (b)(3) of this section.

(iii) Seals on floating membrane covers shall be monitored around the entire perimeter of the cover at locations spaced no greater than 3 meters apart.

(3) When a leak is detected by either of the methods specified in paragraphs (b)(1) or (b)(2) of this section, the owner or operator shall repair the leak in the following manner.

(i) Repair of the leak shall be completed as soon as practicable, but no later than 15 calendar days after the leak is detected. If repairs cannot be completed within 15 days except as provided in paragraph (b)(3)(iii) of this section, the owner or operator shall not add waste to the hazardous waste management unit until the repair is complete.

(ii) A first attempt at repair of each leak shall be made no later than 5 calendar days after the leak is detected.

(iii) Repair of control equipment installed to comply with § 265.1085(b) of this subpart and for which leaks have been detected may be delayed beyond 15 calendar days if the owner or operator documents that the repair cannot be completed without a complete or partial facility or impoundment shutdown and that delaying the repair would not cause the control equipment to be significantly less protective of human health and the environment. Repair of this control equipment shall be completed before the end of the next facility or impoundment shutdown.

(c) The owner or operator shall monitor and inspect each closed vent system and control device in accordance with the following requirements:

(1) The owner or operator shall monitor each control device in accordance with §§ 265.1033(f)(1) and 265.1033(f)(2) of this part. The owner or operator shall inspect at least once each operating day all data recorded by the control device monitoring equipment (e.g., temperature monitors) to check that the control devices are being operated in compliance with this subpart.

(2) The owner or operator shall visually inspect each closed vent system and control device installed initially upon installation of the equipment and thereafter at least once per week. The visual inspection shall include inspection of ductwork and piping and their connections to covers and control devices for evidence of visible defects such as holes in ductwork or piping and loose connections. If visible defects are observed during an inspection, the closed vent system and control device shall be repaired in accordance with paragraph (c)(4) of this section.

(3) The owner or operator shall monitor each closed vent system and control device in the following manner:

(i) Each cover connection and seal shall be monitored initially upon installation of the equipment and thereafter at least once every year in accordance with Reference Method 21.

(ii) If the monitoring instrument indicates detectable emissions (i.e., a concentration above 500 ppmv), then a leak is detected and the leak shall be repaired in accordance with paragraph (c)(4) of this section.

(4) When a defect or leak is detected by either of the methods specified in paragraphs (c)(2) or (c)(3) of this section, the owner or operator shall repair the defect or leak in the following manner:

(i) Repair of the defect or leak shall be completed as soon as practicable, but no later than 15 calendar days after the defect or leak is detected. If repairs cannot be completed within 15 days, then the owner or operator shall not add waste to the hazardous waste management unit until the repair is complete.

(ii) A first attempt at repair of each defect or leak shall be made no later

than 5 calendar days after the defect or leak is detected.

(d) The owner or operator shall develop and follow a written schedule for all monitoring and inspection requirements of this section used to comply with this subpart. The owner or operator shall incorporate this schedule into the facility inspection plan described in 265.15 of this part.

§ 265.1089 Recordkeeping requirements.

(a) An owner or operator placing waste in a hazardous waste management unit using control equipment pursuant to §§ 265.1084, 265.1085, or 265.1086 of this subpart shall record the following information:

(1) Engineering design documentation for each cover that includes:

(i) Cover type,

(ii) Cover manufacturer's name and model number,

(iii) Cover dimensions,

(iv) Materials used to fabricate cover,

(v) Mechanism used to install cover on the waste management unit and seal the cover perimeter,

(vi) Type, size, and location of each cover opening, and

(vii) Mechanism used to close and seal each cover opening identified in paragraph (a)(1)(vi) of this section.

(2) Documentation for each closed vent system and control device that includes:

(i) Certification that is signed and dated by the owner or operator stating that the control device is designed to operate at the performance level documented by paragraph (a)(2)(ii) or (a)(2)(iii) of this section when the hazardous waste management unit is or would be operating at capacity or the highest level reasonably expected to occur.

(ii) If engineering calculations are used, then design documentation as specified in § 265.1035(b)(4) of this part. Documentation provided by the control device manufacturer or vendor that describes the control device design in accordance with § 265.1035(b)(4)(iii) of this part and certifies that the control equipment meets the specifications may be used to comply with this requirement.

(iii) If performance tests are used, then a performance test plan as specified in § 265.1035(b)(3) of this part and all test results.

(iv) Information as required by § 265.1035(c)(1) and (c)(2).

(3) Records for all visual inspections conducted in accordance with § 265.1087 of this subpart.

(4) Records for all Reference Method 21 monitoring conducted in accordance with § 265.1088 of this subpart.

(5) Records for all continuous monitoring conducted in accordance with § 265.1088 of this subpart.

(b) An owner or operator placing waste having a volatile organic concentration equal to or greater than 500 ppmw in a tank pursuant to § 265.1084(b)(2) of this subpart shall record the following information for each tank:

(1) Date, time, and location each waste sample is collected for direct measurement waste determination of maximum organic vapor pressure in accordance with § 265.1083 of this subpart.

(2) Results of each waste determination for maximum organic vapor pressure performed in accordance with § 265.1083(c) of this subpart.

(3) Records specifying the tank dimensions and design.

(4) If the maximum organic vapor pressure of the waste placed in the tank exceeds the maximum organic vapor pressure limit for the tank's design capacity category specified in § 265.1084(b)(2)(i)(D) of this subpart, then an explanation of the reason or reasons why the waste was not managed in accordance with this subpart.

(c) An owner or operator placing waste in a hazardous waste management unit pursuant to § 265.1082(a)(1)(i) of this subpart shall record the following information for each waste management unit:

(1) Date, time, and location that each waste sample is collected for direct measurement waste determination of volatile organic concentration in accordance with § 265.1082(a) of this subpart.

(2) All waste determination volatile organic concentration results from either direct measurements performed in accordance with § 265.1083(a)(1)(i) of this subpart or knowledge documented in accordance with § 265.1083(a)(1)(ii) of this subpart.

(3) If the volatile organic concentration of the waste placed in the waste management unit is equal to or greater than 500 ppmw, then an explanation of the reason or reasons why the waste was not managed in accordance with this subpart.

(d) An owner or operator placing waste in a hazardous waste management unit pursuant to § 265.1082(a)(1)(ii) of this subpart shall record the following information for each waste management unit:

(1) Date, time, and location that each waste sample is collected for direct measurement determination of volatile organic concentration in accordance with § 265.1082(a) of this subpart.

(2) All waste determination volatile organic concentration results from either direct measurements performed in accordance with § 265.1083(b)(1)(i) of this subpart or knowledge documented in accordance with § 265.1083(b)(1)(ii) of this subpart.

(3) If the volatile organic concentration of the waste placed in the waste management unit is equal to or greater than 500 ppmw, then an explanation of the reason or reasons why the waste was not managed in accordance with this subpart.

(e) All records required by paragraphs (a), (b), (c) and (d) of this section except as required in paragraphs (a)(3), (a)(4), and (a)(5) shall be maintained in the operating record until closure of the facility. All records required by paragraphs (a)(3), (a)(4), and (a)(5) of this section shall be maintained in the operating record for a minimum of three years.

(f) The owner or operator of any facility that is subject to this subpart and to the control device regulations in 40 CFR 60 subpart VV or 40 CFR 61 subpart V, may elect to demonstrate compliance with this subpart by documentation either pursuant to this subpart, or pursuant to the provisions of 40 CFR part 60 or 61, to the extent that the documentation under 40 CFR part 60 or part 61 duplicates the documentation required under this subpart.

[Approved by the Office of Management and Budget under control number 2060-____.]

§ 265.1090 Alternative control requirements for tanks.

(a) The owner or operator of a hazardous waste management facility that manages waste in tanks may install and operate one of the following types of control equipment as an alternative to complying with § 265.1084(b)(1).

(1) *A fixed roof and internal floating roof.* The fixed roof shall comply with the requirements of paragraph § 265.1084(b)(1)(i)(A). The internal floating roof shall rest or float on the liquid surface (but not necessarily in complete contact with it) inside a tank that has a fixed roof. The internal floating roof shall be floating on the waste surface at all times, except during initial fill and during those intervals when the tank is completely emptied or subsequently emptied and refilled. When the roof is resting on the leg supports, the process of filling, emptying, or refilling shall be continuous and shall be accomplished as rapidly as possible.

(i) Each internal floating roof shall be equipped with one of the following

closure devices between the wall of the tank and the edge of the internal floating roof:

(A) A foam- or liquid-filled seal mounted in contact with the liquid (liquid-mounted seal). A liquid-mounted seal means a foam- or liquid-filled seal mounted in contact with the liquid between the wall of the tank and the floating roof continuously around the circumference of the tank.

(B) Two seals mounted one above the other so that each forms a continuous closure that completely covers the space between the wall of the tank and the edge of the internal floating roof. The lower seal may be vapor-mounted, but both shall be continuous.

(C) A mechanical shoe seal. A mechanical shoe seal is a metal sheet held vertically against the wall of the tank by springs or weighted levers and is connected by braces to the floating roof. A flexible coated fabric (envelope) spans the annular space between the metal sheet and the floating roof.

(ii) Each opening in a noncontact internal floating roof except for automatic bleeder vents (vacuum breaker vents) and the rim space vents is to provide a projection below the waste surface.

(iii) Each opening in the internal floating roof except for leg sleeves, automatic bleeder vents, rim space vents, column wells, ladder wells, sample wells, and stub drains is to be equipped with a cover or lid which is to be maintained in a closed position at all times (i.e., no visible gap) except when the device is in actual use. The cover or lid shall be equipped with a gasket. Covers on each access hatch and automatic gauge float well shall be bolted except when they are in use.

(iv) Automatic bleeder vents shall be equipped with a gasket and are to be closed at all times when the roof is floating except when the roof is being floated off or is being landed on the roof leg supports.

(v) Rim space vents shall be equipped with a gasket and are to be set to open only when the internal floating roof is not floating or at the manufacturer's recommended setting.

(vi) Each penetration of the internal floating roof for the purpose of sampling shall be a sample well. The sample well shall have a slit fabric cover that covers at least 90 percent of the opening.

(vii) Each penetration of the internal floating roof that allows for passage of a column supporting the fixed roof shall have a flexible fabric sleeve seal or a gasketed sliding cover.

(viii) Each penetration of the internal floating roof that allows for passage of a ladder shall have a gasketed sliding cover.

(2) *An external floating roof.* Each external floating roof shall meet the following specifications:

(i) Each external floating roof shall be equipped with a closure device between the wall of the tank and the roof edge. The closure device is to consist of two seals, one above the other. The lower seal is referred to as the primary seal, and the upper seal is referred to as the secondary seal.

(A) The primary seal shall be either a mechanical shoe seal or a liquid-mounted seal. Except as provided in § 265.1090(b)(2)(iv) of this section, the seal shall completely cover the annular space between the edge of the floating roof and tank well.

(B) The secondary seal shall completely cover the annular space between the external floating roof and the wall of the storage vessel in a continuous fashion except as allowed in § 265.1090(b)(2)(iv) of this section.

(ii) Except for automatic bleeder vents and rim space vents, each opening in a noncontact external floating roof shall provide a projection below the waste surface. Except for automatic bleeder vents, rim space vents, roof drains, and leg sleeves, each opening in the roof is to be equipped with a gasketed cover, seal, or lid that is to be maintained in a closed position at all times (i.e., no visible gap) except when the device is in actual use. Automatic bleeder vents are to be closed at all times when the roof is floating except when the roof is being floated off or is being landed on the roof leg supports. Rim vents are to be set to open when the roof is being floated off the primary seal or the secondary seal (if one is in service) through manholes and roof hatches on the fixed roof at least once every 12 months after initial fill. If the internal floating roof is not resting on the surface of the waste inside the tank, or there is liquid accumulated on the roof, or the seal is detached, or there are holes or tears in the seal fabric, the owner or operator shall repair the items or empty and remove the tank from service within 45 days. If a failure that is detected during inspections required in this paragraph cannot be repaired within 45 days and if the tank cannot be emptied within 45 days, a 30-day extension may be requested from the Regional Administrator in the inspection report required in § 265.1090(c)(1)(ii) of this section. Such a request for an extension shall document that alternate capacity is unavailable and specify a schedule of actions the company will take that will assure that the control equipment will be repaired or the tank will be emptied as soon as possible.

(iii) For tanks equipped with a double-seal system as specified in § 265.1090(a)(1)(i)(B) of this section:

(A) Visually inspect the tank as specified in paragraph (b)(1)(iv) of this section at least every 5 years; or

(B) Visually inspect the tank as specified in paragraph (b)(1)(ii) of this section.

(iv) Visually inspect the internal floating roof, the primary seal, the secondary seal (if one is in service), gaskets, slotted membranes (if any), and sleeve seals (if any) each time the tank is emptied and degassed. If the internal floating roof has defects, the primary seal has holes, tears, or other openings in the seal or the seal fabric, or the gaskets no longer close off the liquid surfaces from the roof leg supports or at the manufacturer's recommended setting. Automatic bleeder vents and rim space vents are to be gasketed. Each emergency roof drain is to be provided with a slotted membrane fabric cover that covers at least 90% of the area of the opening.

(v) The roof shall be floating on the waste at all times (i.e., off the roof leg supports) except during initial fill until the roof is lifted off leg supports and when the tank is completely emptied and subsequently refilled. The process of filling, emptying, or refilling when the roof is resting on the leg supports shall be continuous and shall be accomplished as rapidly as possible.

(3) An alternative means of emission limitation for which a **Federal Register** notice has been published according to the provision of 40 CFR 60.114b permitting its use as an alternative means for purposes of compliance with 40 CFR 60.112b.

(b) Monitoring and inspection of the control equipment described in paragraphs (a)(1) and (a)(2) of this section shall be conducted as follows:

(1) After installation, owners and operators of internal floating roofs shall:

(i) Visually inspect the internal floating roof, the primary seal, and the secondary seal (if one is in service), prior to filling the tank with waste. If there are holes, tears, or other openings in the primary seal, the secondary seal, or the seal fabric or defects in the internal floating roof, or both, the owner or operator shall repair the items before filling the tank.

(ii) For tanks equipped with a liquid mounted or mechanical shoe primary seal, visually inspect the internal floating roof and the atmosphere, or the slotted membrane has more than 10 percent open area, the owner or

operator shall repair the items as necessary so that none of the conditions specified in this paragraph exist before refilling the tank with waste. In no event shall inspections conducted in accordance with this provision occur at intervals greater than 10 years in the case of tanks conducting the annual visual inspection as specified in paragraph (b)(1)(ii) of this section, and at intervals no greater than 5 years in the case of tanks specified in paragraph (b)(1)(iii) of this section.

(v) Notify the Regional Administrator in writing at least 30 days prior to the filling or refilling of each tank for which an inspection is required by paragraphs (b)(1)(i) and (b)(1)(iv) of this section to afford the Regional Administrator the opportunity to have an observer present. If the inspection required by paragraph (b)(1)(iv) of this section is not planned and the owner or operator could not have known about the inspection 30 days in advance of refilling the tank, the owner or operator shall notify the Regional Administrator at least 7 days prior to the refilling of the tank. Notification shall be made by telephone immediately followed by written documentation demonstrating why the inspection was unplanned. Alternatively, this notification, including the written documentation, may be made in writing and sent by express mail so that it is received by the Regional Administrator at least 7 days prior to the refilling.

(2) After installation, owners and operators of external floating roofs shall:

(i) Determine the gap areas and maximum gap widths between the primary seal and the wall of the tank and between the secondary seal and the wall of the tank according to the following frequency.

(A) Measurements of gaps between the tank wall and the primary seal (seal gaps) shall be performed during the hydrostatic testing of the tank or within 60 days of the initial fill with waste and at least once every 5 years thereafter.

(B) Measurements of gaps between the tank wall and the secondary seal shall be performed within 60 days of the initial fill with waste and at least once per year thereafter.

(C) If any tank ceases to hold waste for a period of 1 year or more, subsequent introduction of waste into the tank shall be considered an initial fill for the purposes of paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section.

(ii) Determine the gap widths and areas in the primary and secondary seals individually by the following procedures:

(A) Measure seal gaps, if any, at one or more floating roof levels when the roof is floating off the roof leg supports.

(B) Measure seal gaps around the entire circumference of the tank in each place where a 0.32 cm (0.13 in) diameter uniform probe passes freely (without forcing or binding against seal) between the seal and the wall of the tank and measure the circumferential distance of each such location.

(C) The total surface area of each gap described in paragraph (b)(2)(ii)(B) of this section shall be determined by using probes of various widths to measure accurately the actual distance from the tank wall to the seal and multiplying each such width by its respective circumferential distance.

(iii) Add the gap surface area of each gap location for the primary seal and the secondary seal individually and divide the sum for each seal by the nominal diameter of the tank and compare each ratio to the respective standards in paragraph (b)(2)(iv) of this section.

(iv) Make necessary repairs or empty the tank within 45 days of identification in any inspection for seals not meeting the following requirements:

(A) The accumulated area of gaps between the tank wall and the mechanical shoe or liquid-mounted primary seal shall not exceed 212 cm^2 per meter (10.1 in^2 per foot) of tank diameter, and the width of any portion of any gap shall not exceed 3.81 cm (1.5 in).

(*1*) One end of the mechanical shoe is to extend into the stored waste, and the other end is to extend a minimum vertical distance of 61 cm (24.0 in) above the stored waste surface.

(*2*) There are to be no holes, tears, or other openings in the shoe, seal fabric, or seal envelope.

(B) The secondary seal is to meet the following requirements:

(*1*) The secondary seal is to be installed above the primary seal so that it completely covers the space between the roof edge and the tank wall except as provided in paragraph (b)(2)(ii)(C) of this section.

(*2*) The accumulated area of gaps between the tank wall and the secondary seal shall not exceed 21.2 cm^2 per meter (1.01 in^2 per foot) of tank diameter, and the width of any portion of any gap shall not exceed 1.27 cm (0.50 in).

(*3*) There are to be no holes, tears, or other openings in the seal or seal fabric.

(v) If a failure that is detected during inspections required in paragraph (b)(2)(i) of this section cannot be repaired within 45 days and if the tank cannot be emptied within 45 days, a 30-day extension may be requested from the Regional Administrator in the inspection report required in § 265.1090(c)(2)(iii) of this section. Such extension request shall include a demonstration of the unavailability of alternate storage capacity and a specification of a schedule that will assure that the control equipment will be repaired or the tank will be emptied as soon as possible.

(vi) Notify the Regional Administrator 30 days in advance of any gap measurements required by paragraph (b)(2)(i) of this section to afford the Regional Administrator the opportunity to have an observer present.

(vii) Visually inspect the external floating roof, the primary seal, secondary seal, and fittings each time the vessel is emptied and degassed.

(A) If the external floating roof has defects, the primary seal has holes, tears, or other openings in the seal or the seal fabric, or the secondary seal has holes, tears, or other openings in the seal or the seal fabric, the owner or operator shall repair the items as necessary so that none of the conditions specified in this paragraph exist before filling or refilling the tank with waste.

(B) For all the inspections required by paragraph (b)(2)(vii) of this section, the owner or operator shall notify the Regional Administrator in writing at least 30 days prior to the filling or refilling of each tank to afford the Regional Administrator the opportunity to inspect the tank prior to refilling. If the inspection required by paragraph (b)(2)(vii) of this section is not planned and the owner or operator could not have known about the inspection 30 days in advance of refilling the tank, the owner or operator shall notify the Regional Administrator at least 7 days prior to the refilling of the tank. Notification shall be made by telephone immediately followed by written documentation demonstrating why the inspection was unplanned. Alternatively, this notification, including the written documentation, may be made in writing and sent by express mail so that it is received by the Regional Administrator at least 7 days prior to the refilling.

(c) Owners and operators who elect to install and operate the control equipment in paragraph (a) of this section shall include the following information in the operating record:

(1) *Internal floating roof.* (i) Documentation that describes the control equipment design and certifies that the control equipment meets the specifications of § 265.1090 (a)(1) and (b)(1) of this section.

(ii) Records of each inspection performed as required by § 265.1090(b)(1) (i)–(iv) of this section. Each record shall identify the tank on which the inspection was performed and shall contain the date the tank was inspected and the observed condition of each component of the control equipment (seals, internal floating roof, and fittings).

(iii) If any of the conditions described in § 265.1090(b)(1)(ii) of this section are detected during the annual visual inspection required by § 265.1090(b)(1)(ii) of this section, the records shall identify the tank, the nature of the defects, and the date the tank was emptied or the nature of and date the repair was made.

(iv) After each inspection required by § 265.1090(b)(1)(iii) of this section that finds holes or tears in the seal or seal fabric, or defects in the internal floating roof, or other control equipment defects listed in § 265.1090(b)(1)(ii) of this section, the record shall identify the tank and the reason it did not meet the specifications of § 265.1090(a)(1) or § 265.1090(b)(1)(iii) of this section and describe each repair made.

(2) *External floating roof.* (i) Documentation that describes the control equipment design and certifies that the control equipment meets the specifications of § 265.1090(a)(2) and § 265.1090(b)(2)(ii)–(iv) of this section.

(ii) Records of each gap measurement performed as required by § 265.1090(b)(2) of this section. Each record shall identify the tank in which the measurement was performed, the date of measurement, the raw data obtained in the measurement, and the calculations described in § 265.1090 (b)(2)(ii) and (b)(2)(iii) of this section.

(iii) Records for each seal gap measurement that detects gaps exceeding the limitations specified by § 265.1090(b)(2)(iv) of this section that identifies the tank, the date the tank was emptied or the repairs made, and the nature of the repair.

34. In 40 CFR part 265, Appendix VI is added to read as follows:

Appendix VI to Part 265—Calculation Procedure for Determination of Waste Volatile Organic Concentration

Appendix VI describes the calculation procedure that shall be used to compute the waste volatile organic concentration value for comparison to the limit specified in § 265.1082(a)(1) of this part. Any inferences derived from the value determined by the procedure described in this appendix apply only to those times at which sampling is performed. The procedure makes no attempt to draw inferences to any other times; however, the requirement to sample when the waste volatile organic concentration is expected to be highest suggests that waste concentrations at other times should not exceed the value determined by the procedure.

The mean of the logarithms of the sample measurements is calculated and a t-test is performed to determine whether the waste volatile organic concentration is less than 500 ppmw.

Notation

n_i = number of waste samples selected at the i^{th} time period (for any sampling period, n^i shall be at least 4).

X_{ij} = natural logarithm of the measured volatile organic concentration of the j^{th} sample at time i (i=0,1,2,.....,and j=1,2,...,n_i),

$\bar{X}_i$ = the mean of the X_{ij} at time period i.

$$\bar{X}_i = \sum_j X_{ij}/n_i \qquad \text{(Eq. 1)}$$

s_i = the standard deviation of the X_{ij} at time period i.

$$s_i = \sqrt{\frac{\sum_j X_{ij}^2 - \left(\sum_j X_{ij}\right)^2/n_i}{n_i - 1}} \qquad \text{(Eq. 2)}$$

K_i = degrees of freedom used in t-test at time i:

$$K_i = (n_i - 1) \qquad \text{(Eq. 3)}$$

A t-test is used to determine if the waste volatile organic concentration is below the action level, 500 ppmw. The null hypothesis is that the true geometric mean of samples taken at time i is 500 ppmw (or more); the alternative hypothesis is that it is less than 500 ppmw. The test is conducted at the 0.10 significance level. Critical values of the t-distribution with K_i degrees of freedom (the upper 90th percentage point) are given in Column 2 of Table X.1 and are denoted below as t_i. The null hypothesis for time i is rejected (i.e., the waste is judged to qualify for management in units that are not controlled for organic air emissions) if:

$$\frac{\bar{X}_i - \ln(500)}{s_i/\sqrt{n_i}} < -t_i \qquad \text{(Eq. 4)}$$

Or equivalently, if:

$$\exp(\bar{X}_i + t_i\, s_i/\sqrt{n_i}) < 500 \qquad \text{(Eq. 5)}$$

For waste determinations, X_i is calculated by averaging the logarithms of the measured values using Equation 1. The other values for the t-test, s_i and K_i, are calculated from Equations 2 and 3, respectively.

TABLE VI.1.—PERCENTAGE POINTS OF T-DISTRIBUTIONS

Degrees of freedom, K_i	90-th Percentage point, t_i
1	3.078
2	1.886
3	1.638
4	1.533
5	1.476
6	1.440
7	1.415
8	1.397
9	1.383
10	1.372
11	1.363
12	1.356
13	1.350
14	1.345
15	1.341
16	1.337
17	1.333
18	1.330
19	1.328
20	1.325
21	1.323
22	1.321
23	1.319
24	1.318
25	1.316
26	1.315
27	1.314
28 and over	1.313

35. In 40 CFR part 265, appendix VII is added to read as follows:

Appendix VII to Part 265—Calculation Procedure for Weighted Average Waste Volatile Organic Concentration

Appendix VII describes the calculation procedure that shall be used to compute the weighted average waste volatile organic concentration value for determining if waste dilution has occurrd per § 265.1083(b)(2) of this part. The equation is used to calculate the weighted average volatile organic concentration for all of the waste streams entering the treatment unit. For a waste stream entering the treatment unit having a volatile organic concentration equal to or greater than 500 ppmw, the measured concentration is used in the equation. For a waste stream entering the treatment unit having a volatile organic concentration less than 500 ppmw, the value of 500 ppmw is used in the equation.

$$C = \frac{\sum_{j=1}^{m}(Q_{aj} \times 500\ \text{ppmw}) + \sum_{i=1}^{n}(Q_{bi} \times C_{bi})}{\sum_{j=1}^{m} Q_{aj} + \sum_{i=1}^{n} Q_{bi}} \qquad \text{(Eq. 6)}$$

where

C = volatile organic concentration (ppm by weight)

Qa_j = quantity of each waste stream (j) to be treated that has a volatile organic concentration greater than or equal to 500 ppmw (Mg), concentration as measured at the point described in § 265.1083(a)(1)

Qb_i = quantity of each waste stream (i) to be treated that has a volatile organic concentration less than 500 ppmw (Mg)

Cb_i = the concentration of each waste stream (i) to be treated that is less than 500 ppmw (ppmw), as measured at the point described in § 265.1083(a)(1)

m = the number of waste streams with concentration greater than or equal to 500 ppmw

n = the number of waste streams with concentration less than 500 ppmw.

Part 270—EPA Administered Permit Programs: The Hazardous Waste Management Program

36. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

Subpart A—General Information

37. Section 270.4 is amended by revising paragraph (a) to read as follows:

§ 270.4 Effect of a permit.

(a) Compliance with an RCRA permit during its term constitutes compliance for purpose of enforcement with Subtitle C of RCRA except for those requirements not included in the permit which become effective by statute, or which are promulgated under Subparts AA, BB, and CC of Part 265 of this chapter limiting air emissions, or which are promulgated under Part 268 of this chapter restricting the placement of hazardous waste in or on the land.

* * * * *

Subpart B—Permit Application

38. Section 270.14 is amended by revising paragraphs (b)(5), (b)(8)(vi), and (b)(13) to read as follows:

§ 270.14 Contents of part B: General requirements.

* * * * *

(b) * * *

(5) A copy of the general inspection schedule required by § 264.15(b). Include where applicable, as part of the inspection schedule, specific requirements in §§ 264.174, 245.193(i), 264.195, 264.226, 264.254, 264.273, 264.303, 264.602, 264.1033, 264.1052, 264.1053, 264.1058, 264.1087, 264.1088, and 264.1090.

* * * * *

(8) * * *

(vi) Prevent releases to the atmosphere.

* * * * *

(13) A copy of the closure plan and, where applicable, the postclosure plan required by §§ 264.112, 264.118, ad 264.197. Include, where applicable, as part of the plans, specific requirements in §§ 264.178, 264.197, 264.228, 264.258, 264.280, 264.310, 264.351, 264.601, 264.603, and 264.1084.

* * * * *

39. Section 270.15 is amended by adding paragraph (e) to read as follows:

§ 270.15 Specific part B information requirements for containers.

* * * * *

(e) Information on air emission control equipment as required in § 270.26.

40. Section 270.16 is amended by adding paragraph (k) to read as follows:

§ 270.16 Specific part B information requirements for tank systems.

* * * * *

(k) Information on air emission control equipment as required in § 270.26.

41. Section 270.17 is amended by adding paragraph (j) to read as follows:

§ 270.17 Specific part B information requirements for surface impoundments.

* * * * *

(j) Information on air emission control equipment as required in § 270.26.

42. Part 270 subpart B is amended by adding § 270.26 to read as follows:

§ 270.26 Specific part B information requirements for air emission controls for tanks, surface impoundments, and containers.

Except as otherwise provided in § 264.1083, owners and operators of facilities that require air emission controls for tanks, surface impoundments, and containers shall provide the following additional information:

(a) For closed vent systems and control devices, design and performance information as specified in § 270.24 (b) and (c),

(b) For facilities required to install covers or enclosures to comply with 40 CFR 264 subpart CC or 40 CFR part 265 subpart CC, detailed design specifications.

(c) An emission monitoring plan for both Reference Method 21 and control device monitoring methods, including:

(1) Monitoring point(s),

(2) Monitoring methods for control devices,

(3) Monitoring frequency,

(4) Procedures for documenting exceedances, and

(5) Procedures for mitigating noncompliances.

(d) For tanks managing waste greater than the vapor pressure limits provided in § 264.1083, the predicted tank holding temperatures and ambient temperatures.

(e) For facilities that cannot install control equipment to comply with the provisions of 40 CFR part 265 subpart CC on the effective date that the facility became subject to the provisions of 40 CFR part 264 subpart CC or 40 CFR part 265 subpart CC, an implementation schedule that includes dates by which the control equipment will be installed and in operation. The schedule shall also include a rationale why the installation could not be completed at an earlier date. The controls shall be installed as soon as possible, but the implementation schedule may allow up to 18 months after the effective date that the facility becomes subject to the provisions of 40 CFR part 264 subpart CC or 40 CFR part 265 subpart CC for installation and startup. All units that begin operation 6 months after the promulgation date of the final rule shall comply with the rules immediately (i.e., shall have control equipment installed and operating on startup of the affected unit).

(f) Documentation demonstrating that a waste is in compliance with the applicable land disposal performance standards in 40 CFR part 268, subpart D for the treatment of organic-containing waste and is, therefore, not required to comply with the control and monitoring requirements of 40 CFR part 264 subparts CC or 40 CFR part 265 subpart CC.

(Approved by the Office of Management and Budget under control number 2060– .)

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

43. The authority citation for part 271 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), and 6926.

Subpart A—Requirements for Final Authorization

§ 271.1 [Amended]

44. Section 271.1(j) is amended by adding the following entry to Table 1 in chronological order by date of publication:

TABLE 1.—REGULATIONS IMPLEMENTING THE HAZARDOUS AND SOLID WASTE AMENDMENTS OF 1984

Promulgation date	Title of regulation	Federal Register reference	Effective date
• •	• •	• •	•
(Publication date of final rule).....	Air standards for Tanks, Surface Impoundments, and Containers.	(Insert Federal Register reference of final rule).	(Publication date of final rule plus 6 months).

§ 271.1 [Amended]

44. Section 271.1(j) is amended by adding the following entry to Table 2 in chronological order by date of publication:

TABLE 2.—SELF-IMPLEMENTING PROVISIONS OF THE HAZARDOUS AND SOLID WASTE AMENDMENTS OF 1984

Effective date	Self-implementing provision	RCRA citation	Federal Register reference
• •	• •	• •	•
(Publication date of final rule plus 6 months).	Air standards for Tanks, Surface Impoundments, and Containers.	3004(n).....	(Insert Federal Register reference of final rule).

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Monday
July 22, 1991

Part III

Department of Commerce

Office of the Secretary

Adjustment of the 1990 Census for Overcounts and Undercounts of Population and Housing; Notice of Final Decision

DEPARTMENT OF COMMERCE

Office of the Secretary

[Docket No. 91282-1181]

Decision of the Secretary of Commerce on Whether a Statistical Adjustment of the 1990 Census of Population and Housing Should Be Made for Coverage Deficiencies Resulting in an Overcount or Undercount of the Population

AGENCY: U.S. Department of Commerce.

ACTION: Notice of final decision.

SUMMARY: This is a notice of the final decision of the Secretary of Commerce on the issue of adjusting the 1990 census to correct for overcounts or undercounts of the population in the 1990 Decennial Census. The purpose of this notice is to inform the public of the decision and to explain the basis for the decision.

DATES: The decision is effective on July 15, 1991.

FOR FURTHER INFORMATION CONTACT: Michael R. Darby, Under Secretary for Economic Affairs and Administrator, Economics and Statistics Administration, Room 4848 Herbert C. Hoover Building, United States Department of Commerce, Washington, DC 20230, Telephone (202) 377-3727.

SUPPLEMENTARY INFORMATION: The Secretary of Commerce is required, pursuant to 13 U.S.C. 141, to conduct a decennial census of the population of the United States. The population totals derived from the census provide the basis for the apportionment of seats in the United States House of Representatives, for state legislative redistricting, for determining district boundaries for county and city elections, and for the allocation of federal funds to state and local governments.

In 1987, the Secretary of Commerce decided not to plan for a statistical adjustment of the 1990 census. As a result, a lawsuit was filed by the city of New York and other parties seeking to compel the Department to plan for such an adjustment. Pursuant to an agreement between the parties in *City of New York. et al.* v. *Department of Commerce. et al.*, 88-Civ.-3474 (E.D.N.Y.), the Department undertook a *de novo* review of the adjustment issue in order to make a decision no later than July 15, 1991, on whether to adjust the 1990 census. The purpose of this notice is to inform the public about the Secretary's decision and the basis for the decision.

Final guidelines which aided the Secretary in his decision were published in the **Federal Register** on March 15, 1990 (FR vol. 55, no. 51, part III pp. 9838-9861).[1] They were intended to provide the framework for a balanced consideration by the Secretary of factors relevant to the decision.

The census adjustment decision process was divided into several distinct phases. The first phase was the actual enumeration of the population. The second phase was the conduct of a post-enumeration survey, based on a probability sample of housing units. This sample provided data for two purposes: estimation of the net overcount or undercount of basic enumeration subgroups using capture-recapture methodology, and application of factors for the adjustment of the enumerated counts. The third phase of the process was a determination of the adequacy of the post-enumeration survey as an evaluation and adjustment tool. The fourth and final phase of the process was a decision on the adjustment question by the Secretary based on the published guidelines.

In making his decision, the Secretary relied on the advice of senior officials in the Economics and Statistics Administration, which includes the Census Bureau, as well as other senior advisors. The Secretary also relied on the individual recommendations of the eight members of the Special Advisory Panel appointed to provide independent advice to the Secretary on the adjustment question. In addition, the Secretary considered the public comments submitted to the Department pursuant to a **Federal Register** notice dated May 24, 1991, seeking comments on the question of whether the 1990 Census should be adjusted. The Department received approximately 650 public comments. These comments, as well as the appendices referred to in the following explanation of the decision, are available for public inspection in the U.S. Department of Commerce Central Reference and Records Inspection Facility, room 6020 Herbert C. Hoover Building, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Following is a detailed discussion of the adjustment decision and the basis for the decision. The discussion is in four sections: a summary statement, an analysis of the guidelines, an evaluation of the recommendations of the Special Advisory Panel and a statement of the decennial census procedures.

[1] Proposed guidelines were published in the **Federal Register** on December 11, 1989. The Court has previously considered and rejected a challenge to the guidelines. See *City of New York* v. *United States Department of Commerce*, 739 F.Supp. 767 (E.D.N.Y. 1990).

Dated: July 15, 1991.

Robert A. Mosbacher,

Secretary of Commerce.

SECTION 1—SUMMARY STATEMENT

Statement of Secretary Robert A. Mosbacher on Adjustment of the 1990 Census

Reaching a decision on the adjustment of the 1990 census has been among the most difficult decisions I have ever made. There are strong equity arguments both for and against adjustment. But most importantly, the census counts are the basis for the political representation of every American, in every state, county, city, and block across the country.

If we change the counts by a computerized, statistical process, we abandon a two hundred year tradition of how we actually count people. Before we take a step of that magnitude, we must be certain that it would make the census better and the distribution of the population more accurate. After a thorough review, I find the evidence in support of an adjustment to be inconclusive and unconvincing. Therefore, I have decided that the 1990 census counts should not be changed by a statistical adjustment.

The 1990 census is one of the two best censuses ever taken in this country. We located about 98 percent of all the people living in the United States as well as U.S. military personnel living overseas, which is an extraordinary feat given the size, diversity and mobility of our population. But I am sad to report that despite the most aggressive outreach program in our nation's history, census participation and coverage was lower than average among certain segments of our population. Based on our estimates, Blacks appear to have been undercounted in the 1990 census by 4.8%, Hispanics by 5.2%, Asian-Pacific Islanders by 3.1%, and American Indians by 5.0%, while non-Blacks appear to have been undercounted by 1.7%.

I am deeply troubled by this problem of differential participation and undercount of minorities, and I regret that an adjustment does not address this phenomenon without adversely affecting the integrity of the census. Ultimately, I had to make the decision which was fairest for all Americans.

The 1990 census is not the vehicle to address the equity concerns raised by the undercount. Nonetheless, I am today requesting that the Census Bureau incorporate, as appropriate, information gleaned from the Post-Enumeration Survey into its intercensal estimates of

the population. We should also seek other avenues for the Bush Administration and Congress to work together and address the impact of the differential undercount of minorities on federal programs.

In reaching the decision not to adjust the census, I have benefitted from frank and open discussions of the full range of issues with my staff, with senior professionals from the Economics and Statistics Administration and the Census Bureau, with my Inspector General, and with statisticians and other experts. Throughout these discussions, there was a wide range of professional opinion and honest disagreement. The Department has tried to make the process leading to this decision as open as possible. In that spirit, we will provide the full record of the basis for our decision as soon as it is available.

In reaching the decision, I looked to statistical science for the evidence on whether the adjusted estimates were more accurate than the census count. As I am not a statistician, I relied on the advice of the Director of the Census Bureau, the Associate Director for the Decennial Census and other career Bureau officials, and the Under Secretary for Economic Affairs and Administrator of the Economics and Statistics Administration. I was also fortunate to have the independent counsel of the eight members of my Special Advisory Panel. These eight experts and their dedicated staffs gave generously of their time and expertise, and I am grateful to them.

There was a diversity of opinion among my advisors. The Special Advisory Panel split evenly as to whether there was convincing evidence that the adjusted counts were more accurate. There was also disagreement among the professionals in the Commerce Department, which includes the Economics and Statistics Administration and the Census Bureau. This compounded the difficulty of the decision for me. Ultimately, I was compelled to conclude that we cannot proceed on unstable ground in such an important matter of public policy.

The experts have raised some fundamental questions about an adjustment. The Post-Enumeration Survey, which was designed to allow us to find people we had missed, also missed important segments of the population. The models used to infer populations across the nation depended heavily on assumptions, and the results changed in important ways when the assumptions changed. These problems don't disqualify the adjustment automatically—they mean we won't get a perfect count from an adjustment. The question is whether we will get better estimates of the population. But what does better mean?

First, we have to look at various levels of geography—whether the counts are better at national, state, local, and block levels. Secondly, we have to determine both whether the actual count is better and whether the share of states and cities within the total population is better. The paradox is that in attempting to make the actual count more accurate by an adjustment, we might be making the shares less accurate. The shares are very important because they determine how many congressional seats each state gets, how political representation is allocated within states, and how large a "slice of the pie" of federal funds goes to each city and state. Any upward adjustment of one share necessarily means a downward adjustment of another. Because there is a loser for every winner, we need solid ground to stand on in making any changes. I do not find solid enough ground to proceed with an adjustment.

To make comparisons between the accuracy of the census and the adjusted numbers, various types of statistical tests are used. There is general agreement that at the national level, the adjusted counts are better, though independent analysis shows that adjusted counts, too, suffer from serious flaws. Below the national level, however, the experts disagree with respect to the accuracy of the shares measured from an adjustment, The classical statistical tests of whether accuracy is improved by an adjustment at state and local levels show mixed results and depend critically on assessments of the amount of statistical variation in the survey. Some question the validity of these tests, and many believe more work is necessary before we are sure of the conclusions.

Based on the measurements so far completed, the Census Bureau estimated that the proportional share of about 29 states would be made more accurate and about 21 states would be made less accurate by adjustment. Looking at cities, the census appears more accurate in 11 of the 23 metropolitan areas with 500,000 or more persons: Phoenix, Washington, DC, Jacksonvillé, Chicago, Baltimore, New York City, Memphis, Dallas, El Paso, Houston and San Antonio. Many large cities would appear to be less accurately treated under an adjustment. While these analyses indicate that more people live in jurisdictions where the adjusted counts appear more accurate, one third of the population lives in areas where the census appears more accurate. As the population units get smaller, including small and medium sized cities, the adjusted figures become increasingly unreliable. When the Census Bureau made allowances for plausible estimates of factors not yet measured, these comparisons shifted toward favoring the accuracy of the census enumeration. Using this test, 28 or 29 states were estimated to be made less accurate if the adjustment were to be used. What all these tests show, and no one disputes, is that the adjusted figures for some localities will be an improvement and for others the census counts will be better. While we know that some will fare better and some will fare worse under an adjustment, we don't really know how much better or how much worse. If the scientists cannot agree on these issues, how can we expect the losing cities and states as well as the American public to accept this change?

The evidence also raises questions about the stability of adjustment procedures. To calculate a nationwide adjustment from the survey, a series of statistical models are used which depend on simplifying assumptions. Changes in these assumptions result in different population estimates. Consider the results of two possible adjustment methods that were released by the Census Bureau on June 13, 1991. The technical differences are small, but the differences in results are significant. The apportionment of the House of Representatives under the selected scheme moved two seats relative to the apportionment implied by the census, whereas the modified method moved only one seat. One expert found that among five reasonable alternative methods of calculating adjustments, none of the resulting apportionments of the House were the same, and eleven different states either lost or gained a seat in at least one of the five methods. I recognize that the formulas for apportioning the House are responsive to small changes and some sensitivity should be expected. What is unsettling, however, is that the choice of the adjustment method selected by Bureau officials can make a difference in apportionment, and the political outcome of that choice can be known in advance. I am confident that political considerations played no role in the Census Bureau's choice of an adjustment model for the 1990 census. I am deeply concerned, however, that adjustment would open the door to political tampering with the census in the future. The outcome of the enumeration process cannot be directly affected in such a way.

My concerns about adjustment are compounded by the problems an adjustment might cause in the redistricting process, which is contentious and litigious enough without an adjustment. An adjusted set of numbers will certainly disrupt the political process and may create paralysis in the states that are working on redistricting or have completed it. Some people claim that they will be denied their rightful political representation without an adjustment. Those claims assume that the distribution of the population is improved by an adjustment. This conclusion is not warranted based on the evidence available.

I also have serious concerns about the effect an adjustment might have on future censuses. I am worried that an adjustment would remove the incentive of states and localities to join in the effort to get a full and complete count. The Census Bureau relies heavily on the active support of state and local leaders to encourage census participation in their communities. Because census counts are the basis for political representation and federal funding allocations, communities have a vital interest in achieving the highest possible participation rates. If civic leaders and local officials believe that an adjustment will rectify the failures in the census, they will be hard pressed to justify putting census outreach programs above the many other needs clamoring for their limited resources. Without the partnership of states and cities in creating public awareness and a sense of involvement in the census, the result is likely to be a further decline in participation.

In looking at the record of public comment on this issue, I am struck by the fact that many civic leaders are under the mistaken impression that an adjustment will fix a particular problem they have identified—for example, specific housing units or group quarters that they believe we missed. It does not do so. It is not a recount. What an adjustment would do is add over 6 million unidentified people to the census by duplicating the records of people already counted in the census while subtracting over 900,000 people who were actually identified and counted. The decisions about which places gain people and which lose people are based on statistical conclusions drawn from the sample survey. The additions and deletions in any particular community are often based largely on data gathered from communities in other states.

The procedures that would be used to adjust the census are at the forefront of statistical methodology. Such research deserves and requires careful professional scrutiny before it is used to affect the allocation of political representation. Since the results of the evaluation studies of the survey were made available, several mistakes have been found which altered the certainty of some of the conclusions drawn by my advisors. The analysis continues, and new findings are likely. I am concerned that if an adjustment were made, it would be made on the basis of research conclusions that may well be reversed in the next several months.

It is important that research on this problem continue. We will also continue the open discussion of the quality of the census and the survey and will release additional data so that independent experts can analyze it. We must also look forward to the next census. Planning for the year 2000 has begun. A public advisory committee on the next census has been established and by early fall I will announce the membership of that committee. I have instructed the Census Bureau's Year 2000 task force to consider all options for the next census, including methods for achieving sound adjustment techniques.

I give my heartfelt thanks to the many people who have devoted so much time and energy to this enterprise. The staff at the Census Bureau have demonstrated their professionalism at every turn through the last two difficult years. They executed a fine census and an excellent survey and then condensed a challenging research program into a few short months. I am deeply grateful for their help. Let me reiterate my sincere thanks to the Special Advisory Panel for their substantial contribution. The staff at the Department, especially those in the Economics and Statistics Administration, also deserve praise.

With this difficult decision behind us, we will commit ourselves anew to finding sound, fair and acceptable ways to continue to improve the census process. We welcome the leadership of Congress and other public officials, community groups, and technical experts in maximizing the effectiveness and minimizing the difficulties of the year 2000 census.

July 15, 1991.

SECTION 2—ANALYSIS OF THE GUIDELINES

Analysis of the Guidelines

Introduction

The 1990 census counts should not be changed by a statistical adjustment. This section explains my evaluation of the evidence relevant to each of the eight guidelines that I considered in reaching my decision. Each section begins with a statement of the guideline and a reiteration of the explanation of the guideline contained in the March 15, 1990, **Federal Register** notice. A discussion of the guideline follows. The final section states my conclusions.

Summaries of my conclusions on each of the eight guidelines are set forth below.

Guideline One

Guideline One requires that convincing evidence be offered that the adjusted estimates of the population are more accurate than the census at the national, State, and local levels. In the absence of such evidence, the census counts are concluded to be the most accurate.

At the national level, it is likely that the PES-adjusted estimates reflect more accurately the total population and the racial and ethnic populations of the country. It appears equally clear, however, that the PES omitted large numbers of certain groups—notably black males. We have no information on the location of these persons. In addition, the PES and demographic analysis lead to sharply different conclusions about the accuracy of the census for several age/sex groups at the national level. Although these are not definitive disqualifiers at the national level, they do raise some question as to whether the adjusted figures are more accurate than the census count even at the national level.

The Constitution requires a census every 10 years not just to count the total number of people in the United States but to locate them so that political representation can be allocated to the states and the people in them in proportion to their numbers. I conclude that the primary criterion for accuracy should be distributive accuracy—that is, getting most nearly correct the proportions of people in different areas. Improved numeric accuracy, although in itself desirable, cannot compensate for treating states and individuals less fairly.

At the State and local level the correct statistical analysis for both distributive and numeric accuracy simply has not been completed. The total error model indicates that the adjusted figures tend to be too high but generally closer in numeric terms to the true population than the census counts which tend to be too low. However, there is sufficient uncertainty about the true variance of the adjusted figures that even numeric accuracy has not been definitively

demonstrated. The loss function analysis and hypothesis tests that have been prepared by the Census Bureau to date, although of uncertain reliability, do support the superior accuracy of the census counts versus the adjusted figures when we consider distributive accuracy—or fairness—and use reasonable estimates of the error variance of the alternative DSE. That is, for the Constitutional purposes of the census the available evidence is consistent with the census counts being more accurate than the adjusted counts. There is certainly not sufficient evidence to reject the distributive accuracy of the census counts in favor of the adjusted counts.

I conclude that, in accordance with Guideline One, the census counts are the most accurate count of the population of the United States at the State and local levels. While the preponderance of the evidence leads me to believe that the total population at the national level falls between the census counts and the adjusted figures, that conclusion is not relevant to the determination of distributive accuracy. Thus this guideline weighs in favor of a decision not to adjust.

Guideline Two

I conclude that the considerations pointed to by Guideline Two tend to reject use of the adjusted figures and support use of the census counts. The adjusted figures—like the census counts—are consistent across all jurisdictional levels and of sufficient detail for all purposes. However, the adjusted figures do not appear to be of sufficient quality to be usable for reapportionment and redistricting. First, the distributive accuracy of the census counts is superior as concluded above in my review of the evidence on Guideline One. Furthermore, substantial evidence casts doubt on the homogeneity assumption underlying the entire synthetic adjustment methodology. Even if the tests discussed under Guideline One and based on the homogeneity assumption had proven favorable to adjustment, this evidence would weigh against adjustment. Instead, both considerations imply that the adjusted figures are not of sufficient quality to be usable for reapportionment and legislative redistricting. Thus, this Guideline weighs in favor of a decision not to adjust the census.

Guideline Three

I have previously concluded that the adjusted figures have not been shown to be more accurate than the census enumeration. That is all that is required under Guideline Three to conclude that the census may not be adjusted. There are, however, additional considerations under Guideline Three under which I also conclude the 1990 census should not be adjusted.

It has proved virtually an impossible task to prespecify the adjustment procedure. It is equally impossible to prespecify the Census procedure. However, in the adjustment procedure an individual or responsible group must make choices which have politically significant effects on the counts that can be transparent to those making the choices. This puts the counts at greater risk of being manipulated than the census. There is no evidence of unprofessional or political manipulation in the 1990 PES program.

The results of the adjustment procedure are broadly robust at an aggregate, national level. However, although various alternatives seem to distribute counts in roughly similar ways, small changes in methodology can move seats in the House. It is also true that small changes in the census enumeration can move seats in the House as well, but no individual involved in the enumeration process can predict how. That is not true for the decisions for adjustment that cannot be or were not prespecified.

One of the most problematic parts of the adjusted process was the bundle of statistical techniques contained in the smoothing process. These techniques relied heavily on statistical assumptions, resulted in large changes in adjustment factors, and may very well have led to an overstatement of the undercount. Thus, this guideline weighs in favor of a decision not to adjust.

Guideline Four

Based on the information available, I conclude that an adjustment would adversely affect future census efforts to a greater extent than any adverse effects of a decision not to adjust. The evidence indicates that the controversy over adjustment is likely to have a negative effect on future censuses regardless of the outcome of the adjustment decision. I am concerned that an adjustment would reduce state and local support for future censuses, adversely affect the Department's ability to obtain appropriate funding for future censuses, adversely affect the quality of the work done in the future by temporary census enumerators who are essential in reaching the hard-to-count, subject the Census Bureau to partisan pressures, and create the possibility for political manipulation of future census counts. Thus, this guideline weighs in favor of a decision not to adjust.

Guideline Five

The question whether the chosen method of adjustment would violate the Constitution and federal statutes depends upon the substantive analysis of whether accuracy of the census is improved by an adjustment. Because there are other compelling substantive reasons not to adjust, legal considerations did not provide a basis for my decision.

Guideline Six

An adjustment to the census is a fundamental change in the way we count and locate the persons residing in the United States. I am deeply concerned that if an adjustment is made, it would be made on the basis of research conclusions that may very well be reversed in the next several months. That would be bad for the country and bad for the Census Bureau.

The results of the PES evaluation studies are not yet completely analyzed. Because of the compressed time schedule imposed by the July 15 deadline, the analysis has not been subject to the full professional scrutiny that such important research requires and deserves. To the Census Bureau's great credit, the statistical tools used to calculate and evaluate the adjusted counts are at the cutting edge of statistical research. But such cutting edge research is not tried and true—it requires more thorough scrutiny before it can be used to affect the allocation of political representation and Federal funding.

Nonetheless, the demands of good research must be weighed against the need for a timely decision. In time we may find a way of combining the PES and the census to create counts that better reflect the absolute levels and the distribution of the population. There are sufficient data and analysis to support a decision not to adjust.

Guideline Seven

Any decision will result in some level of disruption through legal challenges. On balance, the record indicates that a decision to adjust would likely be more disruptive than a decision not to adjust. A decision to adjust would clearly cause disruption in those States that have early redistricting deadlines. The assertion that persons are denied their rightful claims without an adjustment assumes that the distribution of the population is improved by an adjustment. Based on the evidence, this assumption is invalid. Thus, this guideline weighs in favor of a decision not to adjust.

Guideline Eight

The requirements for this Guideline have been met. This Guideline does not weigh in favor of a decision either way since the requirements of this Guideline could have been fully met if the decision had been to adjust.

Guideline One

The Census shall be considered the most accurate count of the population of the United States, at the national, State and local level, unless an adjusted count is shown to be more accurate. The criteria for accuracy shall follow accepted statistical practice and shall require the highest level of professional judgment from the Bureau of the Census. No statistical or inferential procedure may be used as a substitute for the Census. Such procedures may only be used as supplements to the Census.

Explanation

The mandate of the Census Bureau is to enumerate the population in a manner that assures that the count of the population is the best achievable given current methodology. As stated in the introduction, the assertion that a method involving statistical inference could lead to a more accurate enumeration warrants close scrutiny.

A set of adjusted counts would be based on a statistical inference that unaccounted for persons were present and that persons who were actually enumerated do not exist or were counted twice. Both determinations are based on a survey of a sample of similar blocks from locations across the country. Thus, the evidence, to be acceptable, must show convincingly that the count can be improved by statistical adjustment at national, state and local levels. In making this assessment, we will examine the effects of the proposed adjustment on the accuracy of counts at all geographic levels.

Comparison of estimates of population size. The estimates of the size of the population from the original enumeration, the demographic analysis, and the post-enumeration-survey estimates will be compared to assess their consistency. The comparison will take into consideration the uncertainty inherent in the demographic analysis and post-enumeration-survey estimates. For the reasons explained in the introduction, the original enumerations will be considered to be more accurate for all geographic areas unless the evidence from demographic analysis and the post-enumeration survey demonstrates convincingly that the dual-system estimate is more accurate.

Accordingly, the Bureau of the Census shall carefully scrutinize and fully describe the size of any net undercount or net overcount inferred from demographic analyses of population sub-groups and the sources of any net undercount or net overcount of population subgroups inferred from the analysis of the post-enumeration survey.

Technical Grounds

Demographic Analysis. Estimates of the size of certain cohorts of the population are based on assumptions about or studies of the behavior of those populations. For some cohorts these assumptions have led to conclusions of net undercounts or net overcounts in several different censuses. The extent to which such conclusions result from specific assumptions will be described. Moreover, the extent to which these assumptions are warranted, and the sensitivity of such conclusions to changes in these assumptions, will be assessed.

The potential sources of error in the demographic analyses the Bureau currently plans are:

Birth registration completeness.
Net immigration of undocumented aliens.
White births, 1915–1935.
Black births, 1915–1935.
Foreign-born emigrants.
Population over age 65.
Models to translate historical birth-record racial classifications into 1990 self-reported census concepts.

The Bureau will examine the effect of errors in each of these measurements on estimates of the net overcount or net undercount. These studies will yield ranges of uncertainty for the demographic estimates of the population which will in turn yield ranges of uncertainty for the net overcount or net undercount. The effect of uncertainty in each of these components will be cumulated into overall levels of potential error.

Post-Enumeration Survey. The capture-recapture method lies at the heart of the post-enumeration-survey models for estimating population coverage deficiencies. The use of this methodology to derive the net undercount or net overcount estimates will be clearly explained. The appropriateness of this methodology to the enumeration of the population will be assessed.

Like demographic analysis, the post-enumeration-survey adjustment mechanism relies on numerous assumptions. The extent to which these assumptions are warranted, and the sensitivity of the conclusions to changes in these assumptions, will be assessed.

Survey methods are based on randomly chosen samples that use statistical inference to estimate the population of the Nation and its components. Such estimates are subject to statistical variation within some range of values—that is, a replication of the process used to make the estimate (including taking the sample) may not lead to the same estimate as the original procedures. Thus, there is a likely range of estimates around the "true" count of the population that depends on the random sample chosen.

If the range of estimates likely to occur is small and near the "truth," then any particular estimate is close to the truth and, thus, acceptable as an approximation of the "truth." If the range is very large, then any particular estimate may not be close to the "truth," and the estimation process gives us little information about the "truth."

A relevant technical criterion related to uncertainty introduced by sampling is how small any possible range of dual-system estimates must be to conclude that any particular outcome of the dual-system estimation process is more accurate than the enumeration itself.

Because the post-enumeration survey itself is a sample, the quantified parameters of the deficiencies are themselves estimates and subject to statistical variability. This variability must be small enough to ensure that any modification of the enumeration is an improvement over the unadjusted counts.

The post-enumeration survey serves two functions. The first function is to detect any deficiencies in the enumeration. For the post-enumeration survey to show convincingly that the enumeration is deficient, it must be clear that the deficiencies are not a result of problems in taking the post-enumeration survey. It follows, then, that the quality of the post-enumeration survey is a central concern in the decision whether to adjust.

The second function is to quantify any deficiencies attributed to the enumeration precisely enough to allow the enumeration to be modified in such a way that we are reasonably certain that the modified enumeration is more accurate than the original enumeration. Thus the post-enumeration survey must quantify the deficiencies of the enumeration precisely and accurately.

How much uncertainty in the measures of deficiency of the enumeration is acceptable?

(1) If the likely range of measures of deficiency would include outcomes that would call for no modification in the

enumeration, then no modification would be done.

(2) The enumeration could be modified if the likely range of measures of deficiency would lead to potential modifications that would be substantially similar in terms of their impact on the counts of demographic groups, their impact on apportionment of Congress, and their impact on local population counts.

The quality of the net overcount or net undercount estimates that result from the post-enumeration survey depends on the quality of a series of operations used to gather and process the required data. The Bureau of the Census will undertake a series of studies to assess the statistical quality of the post-enumeration survey data. The results of these studies will yield measures of the precision and accuracy of the net overcount and net undercount estimates and a range of estimates for the net undercount and net overcount.

The current plans of the Bureau include investigation of the following sources of error for the dual system estimate of population size based on the post-enumeration survey and the census:

Missing data
Quality of the reported census day address
Fabrication in the P sample
Matching error
Measurement of erroneous enumerations
Balancing the estimates of gross overcount and gross undercount
Correlation bias
Random error

These and other component errors will be combined to produce an estimate of the overall level of error. In all evaluations, analyses will examine data for the population as a whole and for race, sex, Hispanic origin, and geographical detail.

Discussion

To certify a set of adjusted counts as the official counts of the population of the United States, one must accept the statistical inferences from a survey that there are persons who were unaccounted for by the census but who were actually present in a specific location on census day, that persons who were actually enumerated either did not exist or were counted twice, and that the same survey, when combined with census counts, can produce more accurate figures than the census enumeration alone. All these inferences are based on information from a sample of 377,381 persons in 171,390 housing units and group quarters in 5,290 block clusters. The people who are inferred to be missing from the census or erroneously enumerated in the census must then be correctly allocated to the specific blocks in which these mistakes were made. These blocks must be chosen out of the 4,830,514 inhabited blocks in the United States. Thus, acceptance of adjusted counts as more accurate requires not only that the counts themselves be shown to be more accurate, but that the distribution of those counts across the United States reflect more accurately the distribution of the population. This is the burden of proof imposed by Guideline One on any decision to adjust the census.

There are three population measurement techniques that play a role in making these statistical inferences. The first is the census enumeration. This was an effort to count each and every person residing in the United States on April 1, 1990. The second is the Post-Enumeration Survey (PES). This is the survey mentioned in the preceding paragraph that was taken several months after census day, independently of the census. An attempt is made to match the persons surveyed in the PES back to records in the census and to match persons in the census to the PES. From the results of this matching process, and a complex web of statistical models, inferences can be made about the number of persons missed by the census and their location. It is the quality of these inferences that is at issue. The third technique is called demographic analysis (DA). DA makes an independent estimate of the population at a national level from administrative records. It can be used to calibrate the results from the census or PES. DA calculates the population from the number of births, number of deaths, the number of immigrants, and the number of emigrants. It builds up a count of the population of the United States from birth and death certificates, immigration records and other sources. Like the census and the PES, DA is also an imperfect measure, so the quality of the inferences made from it are in question as well.

In the course of the discussion of this guideline, various aspects of these three complex processes will be explained and discussed. A detailed explanation can be found in Section Four of this report. We begin by comparing the national counts found in 1990 using these three methods.

A Comparison of the Counts at the National Level Using Three Methods

The national total count from the census enumeration is compared, in Table 1, Appendix 14, with the corresponding total in the proposed adjusted counts based on the PES and also with the corresponding estimates based on DA. The census count is 2.07% or 5,269,917 persons less than the PES estimate. There is evidence of racial, ethnic, and sex differential undercounts in the census when compared to the PES-based estimates. The count of black males in the census was 5.37% or 804,233 persons lower than the population inferred from the PES. The count of black females in the census was 4.33% or 715,543 persons lower than the PES estimated. For non-black males the census count was below the PES estimate by 2.02% or 2,205,443 persons and for non-black females the differential was 1.36% or 1,544,050 persons.

Estimates of national population totals are derived by DA based primarily on administrative records. Demographic analysis estimates provide national totals only and cannot be used to locate people as census counts are required to do. Many argue that the DA estimates broadly corroborate differential undercounts implied by PES-adjusted counts; [1] however, like the minority on the Undercount Steering Committee,[2] I find there are some important and puzzling differences. First, the overall undercount rate inferred from comparing the census to DA (1.85%) is smaller than that inferred from the PES (2.07%). At an aggregate level, the demographic analysis is thought to be more inclusive since the PES and census will miss people who are difficult to survey. Thus the estimate of the population from the PES was expected to be lower than the DA estimate. It is not. The PES estimated total population is 0.23% higher than the DA estimate. More detailed analysis shows that the PES and DA estimates are not far apart in a statistical sense.[3]

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[1] See appendix 7: Bryant, Barbara E., Director of the U.S. Bureau of the Census, "Recommendation to Secretary of Commerce Robert A. Mosbacher on Whether or Not to Adjust the 1990 Census," June 28, 1991, [hereafter Bryant] page 16. See also Appendix 4, "Report of the Undercount Steering Committee," U.S. Bureau of the Census, June 21, 1991, [hereafter Undercount Steering Committee] page 4. See also Appendix 3: Ericksen, Eugene P., Estrada, Leobardo F., Tukey, John W., Wolter, Kirk M. "Report on the 1990 Decennial Census and the Post-Enumeration Survey," Members of the Special Advisory Panel, June 21, 1991, [hereafter Ericksen, *et al.*,] page 10.

[2] Undercount Steering Committee, page 4.

[3] The 95% confidence interval for the overall PES undercount rate is from 1.23% to 2.20% and the judgmental 95% confidence interval for the overall demographic undercount rate is from 1.6% to 3.4%. A confidence interval gives the range of statistically plausible values. The "95%" refers to the notion that one is 95% sure this interval has captured the true, but unknown, value. See table 2 in appendix 14.

Nevertheless, the fact that the direction of difference is the opposite of what statistical experience would have led us to expect raises a troubling question about the relationship between the two methods.[4]

Another example of a gross inconsistency between the PES and DA is that an adjustment would add 1,055,826 more females than DA indicates should be added. If DA were in fact correct, and the enumeration were adjusted, the official population counts would have a 0.82% overcount of females imbedded in it.

The third disturbing comparison between the PES and DA undercount rates is that all groups of black males (except those aged 10–19) are substantially undercovered by the PES relative to DA. This results in PES-based undercount rates that are substantially smaller than the DA rates. This is the type of result that is usually expected in comparing the PES and DA.[5] An adjustment based on the PES would add 804,233 black males to the population. According to demographic analysis, the number of black males that should be added to the population is 1,338,380. Thus the PES-based adjustment would be omitting 534,147 black males according to DA. For black females the PES adjustment would add 29,390 fewer persons than DA indicates should be added. If we accept the DA as being closer to the truth, we could not appropriately add the persons the PES missed to the count because we have no way of locating them.

Some will argue that "going part way" toward remedying the undercount of black males is better than doing nothing.[6] The trouble with this argument is that it ignores the fact that increased accuracy for census counts means not only increased accuracy in the level of the population, but also increased accuracy in the distribution of the population in states and localities. In particular, for the primary uses of the census—apportionment and redistricting—the share or fraction of the total population in a given state, city or precinct is critical. It is this fraction that determines political representation and the amount of Federal funds allocated across political jurisdictions. The paradox is that even if you improve the accuracy in the level of the population in any given city by adding at least some of the people missed in the census, you do not necessarily improve and can worsen accuracy in the share of the population in that city. This point is explored further in the section on how accuracy is measured.

Special Advisory Panel Member Wachter estimates that the number of people missed by both the census and the PES may be as high as half-a-million.[7] We do not know where these people are.[8] The implicit assumption that we would be making if we went ahead and adjusted the count is that they are spread over the country in the same way as the post-adjustment population. Such an assumption has no empirical foundation. There is no doubt that there is a fundamental deficiency in the count, but there is also a fundamental deficiency in the PES. It is not clear that the adjusted counts will accurately reflect relative populations in particular jurisdictions. As Wachter states:

> When we try to gauge the relative sizes of two states or cities or counties or districts [after an adjustment], we must always worry that there are enough more of the unreached in one than in the other to reverse the judgment about relative size that the adjusted counts would lead us to make.[9]

To further complicate matters, at the national level there are instances where a PES-based adjustment to the census would move subpopulation totals in the opposite direction from that indicated by DA:

- An adjustment based on the PES will add 180,318 non-black males aged 10–19, while the DA indicates 136,908 should be deleted, a difference in the wrong direction of 317,226.[10]
- An adjustment based on the PES will delete 91,631 males over the age of 65, while DA indicates that 192,950 should be added, a difference in the wrong direction of 284,541 persons.[11]
- An adjustment based on the PES will add 375,053 females aged 10–19 when DA indicates that 7,141 should be deleted, a difference of in the wrong direction of 382,191.[12]
- An adjustment based on the PES will delete 245,253 females over the age of 45 while DA indicates 146,255 should be added, a difference of 391,508 persons in the wrong direction.[13]

Another grouping of the population that plays a key role in the adjustment process is called a post-stratum. To calculate the adjusted population estimates, the population is broken down into 1392 groups called post-strata. Every individual in the United States fits into one, and only one, of these post-strata. These post-strata are based on census division, type of place of residence, tenure of residence, race, Hispanic ethnicity, sex, and age. These are the smallest groupings of people for which an undercount rate is estimated by the Census Bureau. When post-strata for similar types of persons are combined (for example, all post-strata with blacks, or all post-strata for people age 30–44) the results are largely consistent with expectations.[14] However, there is a lot of variation across the post-strata for similar types of people. Wachter offers intriguing evidence that "the story of census coverage, at a level of fine detail, is more complicated than one would hope." [15] For example, if one looks at all the post-strata for blacks, 25% of them show an overcount rather than an undercount.[16] Thus the broad, national-level aggregations of undercount by race, ethnicity, sex, and age mask a large amount of diversity within those groups. It is therefore overly simplistic to conclude that the census generally results in an undercount for all members of any particular group.

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[4] As will be discussed later, there are measured biases in the production adjustment estimates. When corrections are made for these measured biases, the overall undercount rate measured by the PES falls below that of DA.

[5] The technical term for this is correlation bias.

[6] See Undercount Steering Committee, page 4; See also appendix 3: Ericksen, Eugene P. "Recommendation on 1990 Census Adjustment," Member, Special Advisory Panel, June 21, 1991, [hereafter Ericksen] page 2; See also Appendix 3: Estrada, Leobardo F. "Recommendation on 1990 Census Adjustment," Member, Special Advisory Panel, June 21, 1991, [hereafter Estrada] page 14; See also Appendix 3: Wolter, Kirk W. "Recommendation on 1990 Census Adjustment," Member, Special Advisory Panel, June 21, 1991, [hereafter Wolter] page 4.

[7] See appendix 3: Wachter, Kenneth W. "Recommendations on 1990 Census Adjustment," Member, Special Advisory Panel, June 17, 1991, [hereafter Wachter] page 8.

[8] The implications of this for accuracy are explained at length below.

[9] Wachter, page 8.

[10] The third table in appendix 14 shows that the 95% PES confidence interval for the undercount rate for this group is (0.53, 1.85) with a point estimate of 1.19. Demographic analysis shows a confidence range of (−1.21, 0.65) with a point estimate of −0.92. Thus neither estimate falls in the other's confidence range.

[11] The third and fourth table of appendix 14 show the confidence intervals for undercount rates for blacks and non-blacks separately. For non-blacks in this group, the confidence intervals for the two methods do not intersect, with the PES confidence interval completely less than zero and the DA confidence interval completely greater than zero. For blacks as well, the two intervals do not overlap. The PES spans zero, the DA is completely greater than zero.

[12] In appendix 14 the confidence intervals for this group are given for blacks and nonblacks separately. For non-blacks the intervals for the PES and DA do not overlap. For blacks they do.

[13] The confidence intervals for the four component groups are given in tables 1 and 2 of appendix 14. The intervals are wide enough that the differences may not be statistically significant.

[14] Wachter, pages 9–10.

[15] Wachter, page 10.

[16] Wachter, page 10.

This section has given an aggregate picture of the population using three different measurement instruments—the census, the PES, and DA. It is clear that the census suffers from an undercount, that the undercount is differential across race, ethnicity, and age, but that there is diversity within these groups. There are substantial and statistically different pictures of the population that are drawn by these three methods even at the national level. This is worrisome in and of itself. An adjustment based on the PES will be at face-value substantially different from our demographic estimates at the most aggregate levels. Whether it is an improvement depends not on its ability to add people and to subtract people from the census, but, rather, on its ability to add them and subtract them from the right places.

The Quality of the Census Enumeration

Special Advisory Panel Members Ericksen, Estrada, Tukey and Wolter all condemn the census as being fatally flawed.[17] I concede the census' imperfections, but the critical inquiry under this guideline is not how flawed the census is, but whether the PES can fix it.[18] Census taking is a complex task that must be completed within a short period of time. In an operation employing 350,000 temporary workers spread over more than 400 offices across the country, quality control is a real problem. The management information system the Census Bureau installed allowed the Census Bureau and the panelists to have access to the type of data panelists report. Thus, while identifying the flaws in the census is important for planning the next one, it simply begs the question that Guideline One poses: Is there convincing evidence showing that the adjustment is more accurate than the enumeration?

The Quality of the Alternative Measurement Tools

In considering whether to adjust the population for undercounts, the quality of the tools used to measure and then make an adjustment is important. The two methods that are alternative to the census are DA and the PES.

Demographic Analysis

Demographic analysis is a count of the aggregate population that is not based directly on any census. Instead it is built from administrative records including birth and death certificates, immigration records, and medicare records, among others. Limitations in record-keeping limit demographic breakdowns to those by age, sex, and black/non-black. There is no uniform reporting of ethnicity (*e.g.*, Hispanic origin) or the race of children of biracial couples. Even the same person might be reported as having different characteristics on birth and death records. Because we do not keep records of movements of individuals within the United States this analysis can only be done at the national level.

Furthermore, demographic estimates of the population are continually being changed. No demographic estimates are ever final, as new sources of data and statistical models are used presumably to improve the inferences made about the population. (For example, as a result of the demographic analysis for this census, the estimates of the 1980 population were still being changed as late as last month.) This year the Census Bureau undertook a series of investigations into the quality of the demographic estimates. An important improvement in the estimates was the first attempt to characterize the uncertainty inherent in them with uncertainty intervals about the point estimates. These improvements are reported in the demographic reports D1–D11.[19] Because demographic analysis will not be used in any adjustment, any detailed discussion of its results is foregone. Nevertheless, it is worth noting that the uncertainty intervals have been used in the previous descriptions of consistency of the various estimates of the population.

In an article in *Science,* David Freedman, Professor of Statistics at the University of California at Berkeley, discusses the limitations of DA in some detail.[20] Racial classification procedures vary widely. Incomplete coverage of vital statistics is a problem especially for certain age groups, with further variation by race and sex. In fact the census is used to adjust the birth certificate data that go into DA before DA is used to evaluate the census. Wachter also notes the complexity of DA,[21] and the fact that it is rightly subject to continual revision. He is particularly uncertain about the correctness of the estimates of immigration. He applauds the innovations in the 1990 DA, but quotes his colleague, Wolter, as saying: "The corrections that have been made are indicative of the corrections yet to be named."

The Post-Enumeration Survey and Dual-System Estimates

The Post-Enumeration Survey serves two related purposes. It is used as a measure of the accuracy of the census and it is used together with the census and statistical methods to generate adjusted counts. These adjusted counts are technically referred to as dual-system estimates (DSE). To evaluate the quality of the PES a series of 21 studies was done.[22] There are two questions that the Census Bureau intended to answer with the evaluation of the quality of the PES. First, whether the survey itself was of high enough quality in design and operation to be able to tell us something reliably about the faults of the census. Second, whether the adjusted counts or DSE were significantly more accurate than the census.

The Quality of the PES Survey

The 21 Census Bureau studies were designed to address the issues of quality in the PES and the DSE, some in a quantitative way, some in a qualitative way. They generated volumes of data that have not yet been fully analyzed or understood. Nevertheless, they have generated the basic material on which a judgment must be made regarding a possible adjustment of the census and the effect of that adjustment on the accuracy of the census.[23] In addition some of the panelists did their own studies on various aspects of PES quality. The broad picture that emerges from the analysis of these studies is that the PES was a generally high-quality survey that was well-executed.[24] There is little doubt that the PES detected an overall undercount in the census and a differential undercount at the national level by race and ethnic origin. But there are some problematic areas and disagreements among experts inside and outside the Census Bureau that have an impact on assessing the quality of the adjusted counts generated from the PES.

[17] Ericksen, page 2; Estrada, page 2; See also Appendix 3: Tukey, John W. "Recommendation on 1990 Census Adjustment," Member, Special Advisory Panel, June 18, 1991, (hereafter Tukey), page 3; Ericksen, *et al.*, pages 4–9.

[18] Nevertheless, this was at least the second-best census ever conducted.

[19] See the executive summary of these evaluation projects in appendix 2.

[20] See Appendix 13: Freedman, David A. "Adjusting the 1990 Census," Science, Volume 252, May 31, 1991, [hereafter Freedman] pp. 1233–1236.

[21] Wachter, pages 14–16.

[22] See the executive summary of these evaluation projects in appendix 2.

[23] Under Guideline Six, as explained later, "[i]f sufficient data and analysis of the data are not available in time to publish adjusted counts by July 15, 1991, a determination will be made not to adjust the 1990 census."

[24] See for example Ericksen, *et al.*, pages 12–16 for a good summary of the merits of the PES as a survey. Also see Wachter, page 2.

Missing data. The PES generates its estimate of the undercount by trying to match households it has information about to households in the census. A household survey in the PES that is matched to the census record of that residence means there was no undercount of that household. A non-match means there was an undercount. Matching is a difficult process and sometimes it is unclear whether there is a match or not. It is not an automatic process, rather it requires judgment and discretion. (For example, is a household headed by R. Smith the same as one headed by Bob Smythe?) Ideally, each household in the PES is matched or adequately resolved as not matched and thus missed in the census. Any case which is not resolved becomes "missing data" and, thus, whether those cases would add to or subtract from the undercount is unknown. The lower the missing data rate is, the more accurate the results are presumed to be. Three evaluation projects examined this problem.[25] In general, missing data were not found to be a serious problem; [26] however, there were two troubling findings. First, it is standard practice to impute persons into unresolved match households. The imputation rates for the two parts of the PES, called the "P" and "E" samples, were high: 1.7% and 2.1% respectively, which is equivalent to 3,900,000 and 5,025,000 individuals in the census when weighted up to the national population total estimate. These numbers are the same order of magnitude as the undercounts. Second, the percent of imputation in an evaluation stratum is highly correlated with the size of the undercount in that stratum. Thus, the strata for which there is more doubt about the quality of the adjusted data because of imputation tend to be the same strata for which an adjustment would result in large increases in the population.

Although Ericksen, Estrada, Tukey and Wolter do not find missing data or imputation to be a problem, Wachter raises some basic questions about imputation.[27] The imputation scheme used for the PES is based on a series of assumptions that are mostly guesswork.

Given the assumptions, Wachter finds that this work is of high quality, yet he is hesitant to believe that these assumptions are necessarily valid. To get some idea of whether the assumptions are important he calculates strict upper and lower bounds on the effects of imputation.[28] This analysis shows that if the imputation assumptions were incorrect, the variation in the estimates could be well beyond that expected from sampling error alone. Thus these untested assumptions are critical. They may in fact be correct, but if they are not, the adjusted estimates may be significantly in error. This implies that the estimates in the adjusted counts are subject to more potential error than has been computed.[29]

Matching error. Highly accurate matching is important because matching errors in even a small percentage of cases can significantly affect undercount estimates.[30] Ericksen, Estrada, Tukey and Wolter find the matching process to be of high quality.[31] Although Wachter does not dispute that this is what the studies show, he believes that the estimate for the matching error is too low, because the rematch study "does not, by its nature, expose certain inevitable kinds of matching errors." [32] For example, he notes that the structured nature of the PES interviews could lead to inaccurate and inflated estimates for undercount rates. His evidence, though anecdotal, is suggestive of the fact that the variance due to matching error is conservatively estimated in the total error model.

Erroneous Enumerations in the Census. Erroneous enumerations include people who died before or were born after census day, fictitious people and pets listed as members of a household, twice counted people as well as people enumerated outside the PES matching area. There were a large number of erroneous enumerations in this census and they were differentially distributed. "While the national rate of erroneous enumerations was estimated at 5.4 percent, the rate for Blacks, Hispanics and central city Asians was 7.7 percent compared to 4.4 percent for all others. Minorities in central cities had the highest erroneous enumeration rate at 8.4 percent." [33] The Census Bureau studies indicate that the PES was good at detecting erroneous enumerations, although three processing offices show statistically significant underestimates of erroneous enumerations.[34] The national effect of these errors is small, but the impact on regional totals is unknown.

Ericksen, Estrada, Tukey, and Wolter take the large number of erroneous enumerations as an indictment of the census.[35] Although it is certainly a matter of concern, especially for future census planning, the relevant question is whether the large numbers of erroneous enumerations would affect the accuracy of the proposed adjustment. Wachter considers this question at length.[36]

> Erroneous enumerations and cases with insufficient information are not part of the usual statistical framework for dual-system estimation. Their modeling has received much less attention than the omission rates . . . The PES, however, turns out to show that erroneous enumerations account for a large portion of the variations in net undercounts across areas and post-strata. *This outcome very much complicates the task of understanding and assessing the adjustment process.*[37] [emphasis in the original]

The adjustment factor for a post-stratum is determined by the netting out of two kinds of errors in the census—in technical terms, gross omissions minus erroneous enumerations. One would hope that the predominant determinant of the adjustment would be the number of people missed in the census: areas with high miss rates get high adjustments. What Wachter demonstrates is that the erroneous enumerations—the number of extra people counted—are what is really driving the adjustment: areas with low duplication rates get high adjustments. For example, the three regions with the highest omission rates have very different adjustment rates. Like Wachter, I find it disturbing that "erroneous enumerations account for a large portion of the variations in net undercounts across areas and post-strata." [38]

As Wachter notes, Ericksen, Estrada, Tukey, and Wolter take the high levels of erroneous enumerations as evidence that coverage improvement programs were not finding real people but just adding fictional people to the count.[39]

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[25] See executive summaries of P1, P2, and P3 in Appendix 2.

[26] Estrada, pages 11–13.

[27] Wachter, pages 21–22.

[28] Wachter, page 22.

[29] In a letter submitted on July 11, 1991, Ericksen and Tukey dispute Wachter's concerns over imputation. Professor Wachter was offered an opportunity to respond in the interest of fair play. In his rebuttal letter, submitted on July 12, 1991, Wachter stands by his statements. Both letters are contained in Appendix 16. Wachter correctly notes that his claim was only that "a great deal rests on the correctness of the assumptions in the imputation," not that his alternatives were more reasonable than the ones used.

[30] Comments by Barbara Bailar, Journal of American Statistical Association. (March 19, 1985). Pages 109–111.

[31] Ericksen, page 13.

[32] Wachter, page 20.

[33] Ericksen, *et al.*, page 8.

[34] Estrada, pages 16–17; and the executive summaries of the evaluation studies P9 and P9a in Appendix 2.

[35] Ericksen, *et al.*, pages 7–9.

[36] Wachter, pages 12–14.

[37] Wachter, page 11.

[38] Wachter, page 11.

[39] Ericksen, *et al.*, pages 5–9 and Wachter page 12.

Wachter finds very mixed evidence on this question in comparing the counts in Detroit and Chicago. Late in the census enumeration, Detroit mounted an intense campaign to improve coverage, exceeding that mounted in Chicago. In the aggregate, Detroit did have a slightly higher erroneous enumeration rate, but a much lower omission rate. Thus, coverage improvement may very well have worked. However, for some categories of people, omission rates are roughly the same between the two cities, whereas erroneous enumeration rates are not. Thus, the evidence about coverage improvement is certainly more mixed than Ericksen, Estrada, Tukey and Wolter claim.[40] It is worth noting that Detroit and Chicago are lumped together when adjustment factors are calculated, despite their sizable differences in coverage patterns.

Correlation Bias. To the extent that the PES misses the same people that the census misses it will underestimate the undercount. The technical term for this problem is correlation bias. There are several ways of assessing the extent of this problem, but the basic message given by all of them is the same. There is strong correlation bias in the PES, especially among black males.[41] Ericksen, Estrada, Tukey and Wolter tend to dismiss this problem by noting that the presence of correlation bias results in an underestimate of the undercount, so an adjustment at least goes part way toward solving the problem.[42]

However, the presence of large correlation bias poses a fundamental difficulty for the adjustment procedure. Since there is no way to observe these people directly, the adjustment estimator attempts to include an estimate of these people. They are often referred to as the "4th cell" since they appear in the 4th cell of a 2 by 2 table in which persons in a particular post-stratum are classified as being in or not in the census and in or not in the PES. Unfortunately we have no direct data to verify if the assumptions for estimating the 4th cell are met. One piece of data indicates there may be a problem we do not fully understand. Traditional wisdom has it that males are generally more subject to correlation bias, since past data support the observation that males are more likely to be missed in both the census and the PES.[43] But, in 1990, about one-half of the people added to the estimate of the population from the 4th cell are women. Thus there is reason to doubt that the "fourth cell" numbers are correct. If that were the case the accuracy of the adjustment would be indirect.

One also expects that the number of people added to the adjusted population from the 4th cell should be small and that the estimate of the total population should be "lower than the truth." This is because no one expects that the estimate to fully reflect people missed in both the census and the PES. In past censuses, that has been the case. However, for 1990, the data are not consistent with past experience. Almost 5 million people were added to the estimate of the total population from the 4th cell, and the PES estimate of the total population exceeded the estimate from DA—a very unexpected finding.[44] Taken together, these findings indicate there may be problems in the adjusted count estimates that are not fully understood.

Wachter devotes several pages to the issue of correlation bias or as he calls it "catchability error."[45] His technical worry is that the allocation of this error to the model that measures the total error in the PES is done in an arbitrary fashion. Specifically, the national totals for black and for non-black males in six age groups estimated from DA are divided by the corresponding totals for females. Under the assumption of no correlation bias for females, these ratios are then multiplied by the national totals from the adjustment estimate for females in each group to give the predicted total for males. The differences between these predicted totals and the totals for men given by the calculated adjustment are the resulting national estimates of unreached persons. The method assumes all unreached people are men. This allocation, which critically affects conclusions about the accuracy of the census, is not based on empirical evidence on the distribution of those persons not reached by either the census or the PES, but rather on a formula of convenience. There is no unique way of choosing an allocation scheme. The one chosen is not obviously bad, but whether it is good is speculative and has no basis in fact. Furthermore, the variation in the PES estimates contributed by correlation bias is computed for sex ratios in an "ingenious" but ultimately untenable fashion.[46] It uses the capture probability of those reachable by the PES and census to infer a capture probability for people who intend to evade both the census and the PES.[47]

Wachter's argument over this technical point takes him back to a more fundamental point raised earlier, and also raised by Special Advisory Panel Members Kruskal and McGehee.[48] The PES is based on a statistical technique called "capture-recapture" which is often applied to estimating wildlife, particularly the number of fish in a pond. Fish are caught, tagged, thrown back and some are recaught in a second catch. An estimate of the population of fish can be made from the number of fish who are tagged on the second catch. The analogy made for the adjustment mechanism is that the census is the first catch and the PES the second. The analogy is not close, and it is not routine to adapt the wildlife model to counting the population.[49] The problem that

[40] Wachter, pages 12–13.

[41] See the discussion above.

[42] For example, see Estrada, page 14.

[43] See the discussion of hard to count groups in C.E. Citro and M. L. Cohen, eds., The Bicentennial Census, National Academy Press, 1985, Chapter 5, especially pages 177–186, and pages 224–237.

[44] See also the earlier discussion regarding the differences between DA and the PES at the national level.

[45] Wachter, page 18.

[46] Wachter, pages 18–19.

[47] In their letter submitted on July 11, 1991, Ericksen and Tukey dispute Wachter's concerns over the consistency of DA and the PES. In his rebuttal letter, submitted on July 12, 1991, Wachter stands by his statements. Both letters are contained in Appendix 16. It is difficult to referee this dispute at the eleventh hour, especially since the lateness of the Ericksen/Tukey letter gave little chance for Wachter to prepare a detailed response. It seems however, that even given the recognized inability of the PES to reach certain black males, a PES-based adjustment would have more persons than demographic analysis would indicate. Now suppose, in fact, that one were to use the behavior of those captured by the PES to extrapolate to those missed by both surveys, as Ericksen and Tukey suggest. The estimate of the population would be, at least by Wachter's estimate, yet another half-a-million higher. Then the PES would exceed DA by well over a million people.

Ericksen and Tukey also take Wachter to task for asserting that "[t]here is no evidence we know of that indicates that a substantial proportion of those persons counted neither by the PES nor the census avoided being counted." Ericksen and Tukey have apparently overlooked a well known study by Valentine and Valentine that concludes "one cannot [always] expect traditional interview or self-enumeration procedures to identify individuals of the type missed in the study area. * * * [T]he men were not reported because identification * * * could be detrimental to the economic welfare of the household." Citro and Cohen, *op cit.* pages 236–37.

[48] See Appendix 3: Kruskal, William, "Recommendation to the Secretary on the Issue of Adjusting the 1990 Census," Member, Special Advisory Panel, June 13, 1991, [hereafter Kruskal], page 2; Wachter pages 18–20; and also Appendix 3, McGehee, J. Michael, "Report to Secretary Robert A. Mosbacher on the Issue of Adjusting the 1990 Census," Member, Special Advisory Panel, June 21, 1991, [hereafter McGehee], pages 8–12.

[49] Citro and Cohen, *op cit.*, page 147, make this point clearly.

worries both Wachter and Kruskal is that, using the fishing analogy, some fish are harder to net than others.[50] There are, among fish, some "wily trout" which cannot be caught at all. Similarly some persons are harder to count than others, and some impossible.[51] For a variety of reasons they avoid the census and other forms of registration. The conclusions drawn about the population depend on what assumptions are made about these unreachable people. Different assumptions lead to widely differing results.

McGehee's concern about the application of capture-recapture is related to this notion of countability. The census and enumeration are both done by enumerators of varying skills, in different kinds of geographical areas (urban, rural, inner city, suburb) in an attempt to enumerate people who have different incentives to cooperate with the census or the PES. Thus there is inherent in the process a large variation in the probability of a particular person being enumerated in a particular place by a particular census worker. Further, to see if a person was counted both in the census and the PES a match has to be made—we do not tag people like we tag trout.[52] The ability of the matcher thus comes into play here. McGehee recognizes that there are elaborate mechanisms in place to control for all the potential variation, but many of those mechanisms depend on unverified statistical assumptions about what is important, and are changed after the data are in or after new research is completed.[53]

Total Error Model. An effort was made to produce estimates of expected error in the PES and variability of the estimates derived from the PES in project P16. This is generally referred to as the *total error model* since it was an attempt to combine the errors found in the PES by the other evaluation studies. These estimates of error cannot be made for any detailed groups. Instead, the population is divided into thirteen very broad categories called evaluation strata.[54] The estimates of errors for each evaluation strata are meant to be indicative of the uncertainties due to sampling error and all known components of non-sampling error. Whether the results of this study of large groups holds for smaller groups such as post-strata, states, cities or districts is unclear.[55]

This evaluation technique represents pioneering work on the part of the Census Bureau. It has been refined several times since the beginning of June, and every indication is that more refinements will be made as research on it is completed over the next several months. Nonetheless, some conclusions can be drawn from this project. On the one hand, the errors introduced by measured flaws in the PES process seem small. On the other hand, the model does show that the PES is biased toward overestimating the undercount and that a bias-corrected estimate of the undercount would be about 1.4 percent rather than the production estimate of 2.1 percent. This means about a third of the net undercount adjustment in the DSE comes from bias in the PES.

Furthermore, the undercounts tend to be higher in the minority evaluation strata, as are the biases in the PES. Even after bias correction, the minority evaluation strata show statistically significant undercounts. Ericksen, Estrada, Tukey, and Wolter note that the shift in shares of each evaluation post-strata would be small if the production estimate were corrected for bias.[56] Wachter [57] expresses various concerns about the computation of the total error model and its components as does the minority of the Undercount Steering Committee.[58] The results of this model are used further in assessing the quality of the counts themselves.

The Quality of the Adjusted Counts

The fact that the PES was generally a high quality survey does not necessarily imply that it results in high quality adjusted counts. To the contrary, erroneous enumerations and correlation bias lead to the conclusion that there are serious doubts about the quality of the adjusted population estimates.

To understand the statistical issues involved in assessing the quality of the adjusted counts it is necessary to begin with a summary understanding of three measures of the population that the Census Bureau compared.[59] First there is the census enumeration. Second there are the adjusted counts or the production dual-system estimates (production DSE). Third there is an alternative DSE that corrects for biases found in the production DSE by examination of the evaluation of the PES in the P-studies. The third measure is used to judge the relative accuracy of the census and the production DSE. There are two main elements of concern: (1) whether to test the accuracy of population totals or of population distributions and (2) how such tests should be performed.

Should population totals or population distributions be compared? Acceptance of the PES measure of the national undercount as reasonable is only a necessary—not a sufficient—condition for it to be an adequate instrument to be used to adjust the actual enumerations. There has always been an undercount in the census. The central questions for the Constitutional and statutory purposes of the census are whether the undercount is evenly or differentially distributed across geographical areas and jurisdictions, and whether we know how to reduce the range of any differential undercounts. Indeed Congress has recognized this problem as well.[60]

These questions have not been squarely faced. For the most part, Census Bureau analysts concentrated on whether we know enough to reduce the errors in the numeric counts without regard to whether this increases or decreases the severity of differential undercounts across geographical areas or jurisdictions. That is, they interpreted accuracy as concerned with getting the number of people closer to the truth rather than getting the allocation of the population for the purposes of political representation and funding closer to the truth. The two do not necessarily go together.

An illustration of the problem with using the absolute criterion alone is useful. Suppose you observed an enumeration which missed exactly 5 percent of the people in each and every block. Thus, although 5 percent is missed in each and every block, the proportion of the total population in each block is still estimated correctly. Suppose now that you adjusted this enumeration by increasing the counts in half the blocks by 1 percent and increasing the counts in the other half by 5 percent. On average you would have reduced the undercount of the

[50] Kruskal, page 3; and Wachter, page 18.

[51] See Citro and Cohen, *op cit.*, pages 139–142.

[52] Although often trout lose their tags which poses a similar conceptual problem.

[53] McGehee, pages 8–12.

[54] A list of evaluation strata and their component post-strata are included in the Decennial Census Procedural Documentation, below.

[55] Wachter, page 16.

[56] Ericksen, *et al.*, page 15.

[57] Wachter, page 17.

[58] Undercount Steering Committee, page 6.

[59] These measures will be explained more fully in the course of this discussion. The alternative DSE is also called the "target" population in Census Bureau documents.

[60] Subcommittee Chairman Thomas Sawyer, for example, noted that "If the undercount were evenly distributed geographically and demographically across the population, it probably would not pose the problem that we confront here and the difficulty that we face in asking the Secretary to come to this decision." Hearing before the Subcommittee on Census and Population of the Committee on Post Office and Civil Service, U.S. House of Representatives, January 30, 1990. Serial no. 101–43. page 18.

population by 3 percentage points thus, improving the numeric accuracy of the nationwide total. The numeric accuracy of the absolute level of the count also would have improved for each block. However, the block proportions would now be wrong. Half the blocks would be 2 percent too small and half would be 2 percent too large relative to the average undercount. The absolute criterion would prefer this type of adjustment even though it moves from a situation in which every citizen gets his or her fair share of representation and funding to one in which every citizen got 2 percent too little or 2 percent too much.[61]

It is quite possible this kind of error could occur when the PES misses persons. The PES failure to include large numbers of black males in the adjusted counts could have caused just this kind of error. We simply do not know if it did.

I conclude that the Constitutional and legal purposes for the census must take precedence, and accuracy should be defined predominately in terms of getting the proportional distribution of the population right among geographical and political units. This argues for putting aside the judgment of accuracy based on getting absolute numbers right (numeric accuracy) and instead focusing on the question of whether there is convincing evidence that the accuracy of the population distribution in the adjusted numbers (distributive accuracy) is superior to the distributive accuracy of the actual enumeration. The quality of the adjusted counts themselves must be examined to address this important issue squarely.

What is the criterion for accuracy? Guideline One mandates that the census enumeration "shall be considered the most accurate count of the population of the United States, at the national, State, and local level, unless an adjustment is shown to be more accurate." This guideline requires a series of statistical hypothesis tests at various levels of geography in which the adjusted counts are to be presumed less accurate measures of the population than the actual census enumeration unless there is convincing evidence that the adjusted counts are closer to the true counts than the actual enumeration.

The true population counts cannot be observed. However, classical statistics provides a standard way of approaching the required inference. In accordance with Guideline One, we take as a working (null) hypothesis that the actual enumerations in fact better characterize the true population. The adjusted counts are an alternative measure and the question is whether the available evidence permits us to reject the hypothesis that the census better describes the true population.

We shall see below that the Census Bureau has provided substantial (although not necessarily "convincing") evidence that the adjusted counts are more accurate if accuracy is interpreted to mean numeric accuracy. However, the evidence provided by the Census Bureau tends to support the superior distributive accuracy of the actual enumeration. Thus, since accuracy is interpreted in terms of the fairness of the implied distribution of representation and funds, the Census Bureau report supports the conclusion that the adjusted counts are not more accurate.

The choice of accuracy criterion is crucial because there appears to be a substantial national net undercount in the numeric census counts. Simply correcting for the estimated net undercount can improve numeric accuracy but significantly worsen distributive accuracy. We can see that we missed people in most areas, but we lack a tool which can improve the distribution of population for the purposes of political representation and funding.

How are the tests of accuracy performed?

(a) The Census Bureau Loss Functions

The Census Bureau approach to testing the quality of the adjusted counts relies heavily on showing that the PES was well-executed and that the identified biases in the production Dual System Estimates or adjusted counts (DSE) are small relative to an "ideal" DSE. Unfortunately this type of validation methodology does not work in the present instance because of a basic design flaw: The DSE fits broadly into the class of "certainty-equivalent" predictors which use estimates as if they were known for certain rather than subject to statistical variation. A statistically optimal estimate of the population for an area would take account of this uncertainty.[62] Thus the conclusion that the measured shortcomings of the adjusted counts under consideration (the "production DSE") are small relative to the ideal DSE merely means that the production DSE has a chance of improving accuracy. It is unacceptable to go the next step and conclude that a good production DSE would be more accurate than the actual enumeration.

The production DSE are in fact less accurate than those ideal DSE because (a) the data were less than perfect, and (b) the correct model was not known. The bulk of the Census Bureau effort was aimed at seeing whether these data and modelling problems were disqualifying for the production DSE. It is clear that the production DSE are not unbiased estimates of the differential undercount rates and the DSE procedure overcorrects for the measured undercounts. This is measured in the total error model discussed above. These biases are quantified for thirteen large evaluation strata.

Using the total error quantification, the Census Bureau has generated an alternative Dual System Estimator of the population. It is worth noting here, that the errors in the production DSE are quantified for 13 very large groups of people. These errors are then "parcelled out" to the 1392 post-strata used to calculate an adjustment, the adjustment factors are corrected for these biases, and the alternative DSE is calculated. Since there are also estimates of variance for the DSE, the Bureau actually calculates a statistical distribution of possible alternative DSE. A thousand random draws from this alternative distribution were used to generate estimates which the Census documentation terms "the target population." This is not the true population distribution—which is unobservable—but rather a tool for assessing the quality of production DSE counts relative to an "ideal" DSE based

[61] Kruskal gives a similar example on page 7 of his recommendation. See also Citro and Cohen, *op cit.*, page 318. "While synthetic estimation is suggested for adjustment, because of its arithmetic and computational simplicity, synthetic estimation is not necessarily an improvement over the census count." Cohen and Citro use a numerical example as an illustration.

[62] The optimal estimate would average the ideal DSE estimate (based on the correct model and perfect data) with the actual enumeration with more weight being put on the actual enumeration when the model parameters are less precisely estimated. In point of fact, there are statistical theorems which demonstrate that even if the correct statistical model were known and perfect data were used, the Dual System Estimator (DSE) could generate adjusted counts which are either (1) clearly less accurate, or (2) not significantly more nor less accurate, or (3) clearly more accurate measures of the true population than the actual enumeration from the census. The question is which of these occurred? A textbook analysis of the suboptimality of the certainty equivalent approach is found in Arnold Zellner, An Introduction to Bayesian Inference in Econometrics, New York: John Wiley & Sons, 1917, pages 322–327. Intuitively, the problem arises because a full correction is attempted which is optimal only if one knows exactly the undercount or overcount in each area. As the actual uncertainty increases about exactly where and how many people were missed, attempts to make the full estimated correction increase the error variance relative to optimal and eventually, if uncertainty is large, relative to the unadjusted counts.

on more perfectly measured data and more correct models. But this hypothetical DSE is also just an estimator—subject to statistical error. So a correct analysis must account for two errors: (1) the error that comes from using the production DSE rather than the idealized DSE and (2) the error that is inherent in the idealized DSE. Then that combined error should be compared with the error in the actual enumeration.

To make matters even more complicated, legislative—and, now, judicial—representation must be apportioned and allocated over many levels of government into districts that treat their residents as fairly as practicable. Thus, comparisons must be made not only at the various levels of government on which funding is based, but down to the census blocks which are the basis for drawing district lines for Federal, State, and local elections. Unfortunately, the Census Bureau did not have the time to conduct the hypothesis tests required by Guideline One before the Undercount Steering Committee report was completed on June 21, 1991. The method they used instead to make these comparisons is called loss function analysis.

In brief, loss function analysis is used to compare two sets of counts for the same population. Ideally, one of the sets of counts is the true population, and thus the loss in accuracy from using the alternative set of counts is measured. In practice, however, the truth is not known, so care must be taken in the interpretation of results. A loss function analysis can be performed at any level of geography—states, counties, cities, precincts, or blocks.

As an example, suppose a loss function analysis is being calculated for states. The difference between the two estimates of the population is calculated for each state. Then some kind of average is taken of the differences across all states to get an aggregate measure of total loss. The differences may be squared, summed and the total divided by the number of states. Alternatively, the absolute values of the differences may be averaged, where the average is weighted by the size of the state. There are an infinite number of formulas that can be used to average the state-by-state losses to get a single measure of total loss. These formulas are called "loss functions," and the results of any analysis can depend heavily on which loss function is chosen. For example, the loss function that uses squared differences penalizes a few large errors much more heavily than many small errors. The absolute value loss function does not have this property. The choice of a loss function is not scientific. It is usually made on the basis of convenience or tradition.

One more general comment on loss function analysis is needed. The loss function is ideally suited to measuring loss when an estimator of a population count is being compared to a known true count. In this case, the interpretation of the loss is straightforward. It is the accuracy lost by using the estimator. However, when one imperfect estimator is being compared to another, it is more difficult to interpret the loss of one estimate. The temptation is to call one estimator the "truth" and measure loss against it. But one is not measuring loss against the truth. This is simply measuring loss of one estimate against another. There is no reason to think this analysis tells you anything about the truth. In loss function analysis, it is critical to consider the base being used for comparison—losses are measured only relative to that base.

The loss function analysis run by the Census Bureau asked whether the enumeration or the production DSE was closer to the "ideal" DSE.[63] This does not form a statistical test of whether the production DSE are more or less accurate than the census counts. It only calculates which set of numbers on average is closer to another set of estimates (the target population). These tests were simply not proper statistical tests to address the critical hypothesis about the distributive accuracy of the PES and the census enumeration.

Their examination of this closeness question erred further in two significant ways: (1) Instead of comparing the production DSE that would be used, they compared the mean of 1000 draws from a model reflecting the statistical properties of the DSE. This effectively eliminates the inaccuracies derived from using one particular set of adjustments. (2) Rather than using Guideline One's mandate that the actual enumeration be deemed more accurate unless the adjusted counts are shown convincingly to be more accurate, the Census Bureau did the reverse—they preferred adjusted counts if the actual enumeration was not proven more accurate.[64] Thus the Census Bureau loss function analysis was seriously deficient.

There is, nonetheless, a June 27, 1991, Addendum to the Undercount Steering Committee report of June 21, 1991, that corrects some initial flaws in the loss function analysis.[65] This addendum attempts to correct for the error in failing to allow for the fact that the target population was itself an estimator subject to random variance. An allowance for this variance was removed from the variance charged to the census counts and estimates made of the number of states for which the population proportion would be made less accurate was generated. The number of state proportions worsened depends crucially upon the allowance made for variance in the alternative DSE: If only the variance measured in the total error model is used, then the shares of an estimated 21 states are made worse by adjustment (using an absolute value loss function).[66] However, this is clearly a minimum estimate. "As a matter of judgment, the total understatement of variance of the estimates from the smoothing model may be in the range of a factor of 1.7 to 3.0 in terms of variance," according to the Undercount Steering Committee.[67] Allowing for a variance factor of 2.0, which is near the lower end of the Undercount Steering Committee range, the proportional shares of about 28 or 29 states would be worsened by an adjustment in terms of distributive accuracy.[68]

Even with the variance factor set at only 1.0, adjustment is estimated to have worsened distributive accuracy compared to the census counts in 11 of the 23 metropolitan areas in cities with 500,000 or more persons: Phoenix, Washington, DC, Jacksonville, Chicago, Baltimore, New York City, Memphis, Dallas, El Paso, Houston, and San Antonio. Again using only the measured variance, half of the 14 metro areas in counties with over 500,000 persons are made less accurate proportionally by

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[63] This loss function analysis is described in detail in Undercount Steering Committee, pages 6–7; and Bryant, pages 12–14.

[64] This last error may reflect the fact that the Census Bureau ignored the difference between the true population and its own approximate ideal estimator. See for example, the Undercount Steering Committee, page 2: "Time did not allow for full simulations of accuracy for smaller areas. There was some evidence from the loss function analysis, but there was no independent evidence with which to compare it: . . . Even so, in the absence of direct evidence to the contrary, the majority concludes that adjusted counts are generally more accurate at lower levels."

[65] A discussion of how this change affected the Undercount Steering Committee's conclusions is contained in the discussion of Guideline Six, below

[66] See Appendix 5. Addendum to the Undercount Steering Committee Report, July, 1991. [hereafter Addendum], page 3. Given the original erroneous analysis, the Undercount Steering Committee report (page 6) was formulated when the committee thought the accuracy of only about 11 states was worsened by adjustment.

[67] Undercount Steering Committee, page 5. The actual variance is believed to substantially exceed the measured variance because of doubts similar to those raised by Wachter for the matching and imputation procedures.

[68] Addendum, page 4.

adjustment. Only aggregate measures are available for areas of other sizes. These show that on average the adjusted figures improve distributive accuracy relative to the census, but no detail is given as to the number of jurisdictions for which the PES is closer than the census. In all these sub-state cases, too, the estimated distributive accuracy of the adjusted figures deteriorates dramatically compared to the census if the variance is increased to allow for the unmeasured uncertainty in the estimator.

In sum, the corrected Census Bureau estimates of distributive accuracy marginally favor the adjusted counts—though many states and communities would be less accurate—*if* only the measured variance is used. When the variance is increased into the plausible range (in the professional judgment of the Undercount Steering Committee), distributive accuracy comparisons are more favorable to the census counts.

It is worth reiterating that Guideline One specifically places the burden of proof on the adjusted estimates, not on the census. The census is considered to be more accurate unless the adjusted figures are shown to be more accurate. With respect to places under 100,000 population there is no direct evidence that adjusted counts are more accurate.[69]

What evidence there was based its conclusions primarily on the numeric accuracy of the adjusted counts rather than the adjusted proportions, and that the Bureau depended upon indirect evidence rather than direct tests of statistical hypotheses.[70]

(b) Face validity tests

In addition to Loss Function Analysis computed by statisticians, demographers at the Census Bureau made an independent evaluation of the adjusted population counts for states. To do this they compared the adjusted state counts with counts simulated by DA. To make the simulations (because DA provides data only at the national level), they disaggregated census counts for each state by race and Hispanic ethnicity. They then applied DA national undercount rates to black and non-black subpopulations and PES rates to Hispanic and Asian and Pacific Islanders. Then they built up new state estimates by recombining the racial and ethnic groups. These simulated state estimates further confirmed the "face validity," or reasonableness, of the adjusted state counts.[71] These face validity tests depend critically on what the analyst expects. Face validity tests certainly cannot be a substitute for formal tests, but just as face validity can be used to show that adjustment is making counts more accurate, face validity can show the opposite.

For example, is it reasonable that New Mexico has the highest undercount rate of any state? Why should the undercount rate for Montana be higher than that of New York State? How can the very low estimated undercount rates in cities like Philadelphia be explained? Of the large cities, only Washington, DC and Boston showed increases in their black populations between 1980 and 1990. Yet, Washington DC is estimated to have a very large undercount rate and Boston is estimated to have a very small undercount rate. Why are the only estimated overcounts for cities over 100,000 concentrated in New England? Why should Akron and Dayton have high estimated undercount rates (3.0% and 3.3%, respectively) and Cleveland have such a low estimated undercount rate (1.4%)? These examples illustrate as above the point noted above that was raised by Wachter earlier—there is much more texture to the pattern of undercount that lies well beneath the surface of any aggregate loss function analysis. Face validity cuts both ways. And the face validity of the proportions of persons in states and localities has not even been checked.

(c) Ericksen, Estrada, Tukey, and Wolter's claims regarding accuracy

These panelists take a different approach to the problem of accuracy of the counts at state and local levels. An article by Wolter and Causey attached to their jointly authored document [72] argues that accuracy improves, on average, at lower levels, so long as the measured undercounts at aggregate levels tend to have smaller errors than the original enumeration. In addition it is argued in a similar manner in an attachment to the joint report that Ericksen, Estrada, Tukey and Wolter submitted that adjusted counts will on average improve block level data (and thus data for localities) consistent with its improvement of data at larger units of geography.[73] Thus their argument asserts that by applying the total error model to the 13 evaluation post-strata, the PES is shown to be more accurate than the census and the error in the PES is shown to be low. They conclude, based on the theoretical argument by Tukey and the empirical argument made by Wolter and Causey, that

a. The total combined error increases as the size of the group decreases; *e.g.*, the combined errors for 5 million blocks will be larger than the combined errors for 1392 post-strata.

b. Consequently, the improvement in amount due to adjustment will be nearly the same for larger and smaller groups, the improvement in percentage terms decreases, but does not change sign, as the groups become smaller.[74]

Ericksen, Estrada, Tukey, and Wolter note that these conclusions depend on a particular measure of combined error—a loss function that uses a size-weighted sum of relative error. Their primary point is that, with such an error measure, conclusions about local accuracy can in fact be drawn from accuracy conclusions at larger levels. In short, they contend, "improvement in quite large areas thus prophesies improvement in very small areas, as well as a variety of intermediate levels." They see a post-enumeration survey with small measured error (and some, like Wachter and the Undercount Steering Committee contend that such error is very conservatively measured) for thirteen large evaluation strata. They conclude that the adjusted counts for these large evaluation strata are more accurate—a questionable inference because they made no formal statistical test of this hypothesis. From this

[69] The Undercount Steering Committee report states "in the absence of direct evidence to the contrary, the majority concludes that adjusted counts are generally more accurate at lower levels," and later "while analysis was not available for smaller areas, the majority concludes that acceptable patterns would happen there also." (Undercount Steering Committee, page 2.). The reasoning is contrary to the explicit mandate of the guideline. Similarly the Director stated, "there is little evidence to judge whether the proportional distribution of adjusted counts is more accurate for places under 100,000. However, Loss Function Analysis shows that for metropolitan places of less than 25,000, 25,000–49,000 and 50,000 or more, and for nonmetropolitan places less than 25,000, and 25,000–49,000 in total, by these sizes categories, adjusted counts are more accurate than the census. However, there are concerns about the accuracy of the loss function assumptions for small areas." (Bryant, page 14.)

[70] In a June 28, 1991, memorandum Senior Mathematical Statistician Robert Fay reports his efforts at conducting formal hypothesis tests of the distributive accuracy of the adjusted figures at the state level only. There was not time for the Undercount Steering Committee to review this memorandum and it may contain further errors. Nonetheless, although the hypothesis tests rejected the superior distributive accuracy of the census counts if only the measured variance was changed to the adjusted figures, the superior accuracy of the census counts was easily accepted for a variance factor of 2.0 and appears (by interpolation) acceptable at any variance factor in the Undercount Steering Committee's plausible range of 1.7 to 3.0.

[71] Bryant, page 14.

[72] See appendix G of Ericksen, *et al.*

[73] See appendix F of Ericksen, *et al.*

[74] Ericksen, *et al.*, page 20.

questionable conclusion they apply mathematical theory to infer *average* accuracy improvements at lower levels.

In testimony before Congress, an official of the General Accounting Office raises some questions on the issue of sampling error and lower level geographic accuracy:

> We believe the amount of sampling error, or variability, deserves attention by the Secretary because it was a consistently high source of uncertainty in the PES over- and undercount estimates. The PES estimates are based on samples and therefore subject to random error. The levels of sampling variation measured by the evaluations of the PES were generally much higher than anticipated by the original design of the PES. For example, even after smoothing to reduce sampling variability, PES over- and undercount estimates for 4 of the 13 evaluation groups did not show a statistically significant difference from the census count. In other words, due to the variability resulting from doing a sample, *the Secretary cannot be sure whether 4 of the 13 population groups reviewed in the Bureau's evaluation of total error in the PES were overcounted by the census, undercounted, or if the census count was correct.* (emphasis added)
>
> The need for precision is especially important because the Bureau's procedure for carrying down PES adjustment factors to lower geographic levels applies the same adjustment factors to large numbers of people over wide geographic areas with similar demographic characteristics.[75]

The Wolter/Causey paper does not address this argument directly. In addition, Wachter argues cogently against indiscriminate use of the Wolter/Causey paper:

> Theirs is a very interesting paper, but its relevance is limited by its concentration on highly aggregated summary measures of improvement. It does not present explicit results on how many units at various levels might be made worse and how many made better by an adjustment. Furthermore, important calculations in the paper depend on stylized assumptions about correlations in the components of the undercount which may or may not hold in fact either for previous PES-like data or for the 1990 PES. These prior studies are valuable, but they are no substitute for examination of the actual 1990 data.[76]

There are fundamental difficulties with the Wolter/Causey argument. I am not convinced that at the evaluation strata level we can conclude the PES is more accurate. First, the measured bias alone is one-third of the total undercount and the Undercount Steering Committee itself stated that there are other non-measured sources of error.[77] Wachter also raises several fundamental concerns about this measurement. Second, the analysis depends on a particular loss function that weights a few large relative errors more than many small ones. This is not inherently bad, just arbitrary.[78] Wachter perhaps summarizes it best:

> *I do not believe that any highly aggregated index or loss function is appropriate for summing up overall accuracy.* It is informative to understand how much the outcomes of calculations with different versions of such aggregated indices differ. But the choice among them is not a scientific choice. Each such index involves implicit value judgments about different sorts of error. For example, each index determines whether a few large errors are more serious that a great many smaller errors. *Whether we agree with a particular tradeoff is a matter of personal and political values. It should not be disguised as science.*[79] [emphasis in original]

Loss functions mask the incredible complexity of the adjustment operation behind a single number. To get a glimpse of this complexity, it is useful to look at the undercount rates by state. Table 1 and Figure 2 of Appendix 10 show the undercount rate by state with margins of error. Counting the District of Columbia as a state, 42 of the 51 states show an undercount rate that is statistically significant. More importantly, however, is how these undercount rates differ from the national average, since it is these differences that determine which states win and which lose. Table 6 and Figure 1 of Appendix 10 show these differences again with margins of error. Only 18 of the 51 states have an undercount rate that is significantly different from the national average. That means in 33 states we do not know if the undercount rate is higher, lower or the same as the national average. Put another way, we do not know if these 33 states deserve more or less political representation and Federal funding than they are receiving. We do not know for these 33 states if an adjustment would result in a more equitable distribution of political representation and resources.

There are winners and losers from an adjustment—that is to be expected whenever a fixed set of resources is going to be divided. More seriously, however, there is general agreement that there will be some localities' counts that will be made less accurate by an adjustment. The proponents contend that, on average, more areas are made accurate, or more people live in areas whose counts are more accurate, or on average the counts are more accurate. These are all vague and general statements that do not describe the areas of the country where accuracy is likely increased and decreased, the types of towns where accuracy is likely increased and decreased, the neighborhoods where accuracy is likely increased and decreased. We have already seen above that general statements about improved accuracy on average are little if at all justified if realistic values are used for the error variance of the alternative DSE. Furthermore, the rhetoric, if not always the analysis, is centered around absolute levels of the counts, not improvements in the distribution of the counts.

Conclusions

Guideline One requires that convincing evidence be offered that the adjusted estimates of the population are more accurate than the census at the national, State, and local levels. In the absence of such evidence, the census counts are concluded to be the most accurate.

At the national level, it is likely that the PES-adjusted estimates reflect more accurately the total population and the racial and ethnic populations of the country. It appears equally clear, however, that the PES omitted large numbers of certain groups—notably black males. We have no information on the location of these persons. In addition, the PES and demographic analysis lead to sharply different conclusions about the accuracy of the census for several age/sex groups at the national level. Although these are not definitive disqualifiers at the national level, they do raise some question as to whether the adjusted figures are more accurate than the census count even at the national level.

The Constitution requires a census every 10 years not just to count the total number of people in the United States but to locate them so that political representation can be allocated to the states and the people in them in proportion to their numbers. I conclude that the primary criterion for accuracy should be distributive accuracy—that is, getting most nearly correct the proportions of people in different areas. Improved numeric accuracy, although in itself desirable, cannot compensate for treating states and individuals less fairly.

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[75] See appendix 17. General Accounting Office. "1990 Census: Applying PES Results and Evaluations to the Adjustment Decision." Testimony before the Subcommittee on Census and Population, Committee on Post Office and Civil Service House of Representatives. [hereafter GAO Report]. Pages 7–8.

[76] Wachter, page 2.

[77] Undercount Steering Committee, page 5.

[78] Indeed, Ericksen, Estrada, Tukey, and Wolter make no claim of uniqueness for their choice of loss function. As noted earlier, the choice of loss function can control the results of an evaluation.

[79] Wachter, page 5.

At the State and local level the correct statistical analysis for both distributive and numeric accuracy simply has not been completed. The total error model indicates that the adjusted figures tend to be too high but generally closer in numeric terms to the true population than the census counts which tend to be too low. However, there is sufficient uncertainty about the true variance of the adjusted figures that even numeric accuracy has not been definitively demonstrated. The loss function analysis and hypothesis tests that have been prepared by the Census Bureau to date, although of uncertain reliability, do support the superior accuracy of the census counts versus the adjusted figures when we consider distributive accuracy—or fairness—and use reasonable estimates of the error variance of the alternative DSE. That is, for the Constitutional purposes of the census the available evidence is consistent with the census counts being more accurate than the adjusted counts. There is certainly not sufficient evidence to reject the distributive accuracy of the census counts in favor of the adjusted counts.

I conclude that, in accordance with Guideline One, the census counts are the most accurate count of the population of the United States at the State and local levels. While the preponderance of the evidence leads me to believe that the total population at the national level falls between the census counts and the adjusted figures, that conclusion is not relevant to the determination of distributive accuracy. Thus this guideline weighs in favor of a decision not to adjust.

Guideline Two

The 1990 Census may be adjusted if the adjusted counts are consistent and complete across all jurisdictional levels: national, State, local and census block. The resulting counts must be of sufficient quality and level of detail to be usable for Congressional reapportionment and legislative redistricting, and for all other purposes and at all levels for which census counts are published.

Explanation

This guideline acknowledges that the population counts must be usable for all purposes for which the Census Bureau publishes data. The guideline also reinforces the fact that there can be, for the population at all geographic levels at any one point in time, only *one* set of official government population figures.

Thus, the level of detail must be adequate to produce counts for all such purposes. If the 1990 Census count is to be adjusted, it must be adjusted down to the census block level. It must be arithmetically consistent to eliminate confusion, and to prevent any efforts to choose among alternative sets of numbers to suit a particular purpose.

If the Census is to be adjusted, a process called synthetic adjustment will be used. A synthetic adjustment assumes that the probability of being missed by the census is constant for each person within an age, race, Hispanic origin, sex, and tenure category in a geographical area. A synthetic adjustment is performed in two steps. First, the preferred adjustment factors are estimated for a variety of post strata defined by age, race, Hispanic origin, sex, and tenure within geographic areas. Then the adjusted estimate in each category for a census block is obtained by multiplying the unadjusted census estimate in that category by the adjustment factor. The adjusted census estimate for the census block is computed by adding the estimated adjustments for each post strata cell of the block. Put simply, in an adjusted population count each individual enumerated will receive a relative weight according to his or her race, age, sex, ethnic background, tenure, and place of residence. The aggregate counts will then be built up from the weighted individuals to census block, local area, state and national counts.

We will conduct evaluations of small area estimations to ensure that this process results in counts that are in fact more accurate.

Evaluations of small area estimation. Coverage error may vary substantially within the post-enumeration-survey post-strata, although the post-strata were drawn to be homogeneous with respect to expected coverage error. The goal of this analysis is to determine whether or not the assumptions underlying a synthetic adjustment of the census are valid and produce counts which are more accurate at all geographic levels at which census data are used. In particular, the within-strata block-to-block variance in characteristics and net overcounts or net undercounts will be analyzed.

Discussion

If I had determined that an adjustment should have been undertaken, the Census Bureau would have issued block-level Public Law 94-171 tapes that would have replaced those issued in the first three months of this year. Replacement Summary Tape File (STF) data would have also been issued and all future census products would have used adjusted counts. Our ability to have done so would have satisfied the production requirements of this guideline.

The substantive question here is whether the adjusted counts are of sufficient quality to be used for all purposes for which census counts are published. Clearly the quality of the adjusted figures is intimately related to their accuracy, which, as the discussion of the preceding Guideline shows, does not compare favorably with the actual enumeration. This Guideline raises another issue—synthetic adjustment.

As explained earlier, the adjustment process uses a survey of persons in 5,290 block clusters to change the number of people in 4,830,514 blocks. Based on extrapolation from this survey 6,188,204 unidentified persons are added by duplicating records of people counted in the census, and 918,937 people who were actually counted in the census are deleted. The adjustment process is done by dividing the population of the country into 1392 groups. Each member of one of these groups is assumed to have the same probability of being missed in the census as every other member of that group. The real quality of the census in a given block or even a given city has little impact on the adjustment of the count of the population of that block or that city. As will be seen in the discussions of Guidelines Seven and Eight, most local officials think that the adjustment will fix particular problems that they have identified in the count for their towns. It would do no such thing.

A synthetic adjustment assumes that the probability of being missed by the census is constant for each person within an age, race, Hispanic origin, sex, and tenure category in a geographic area. These groupings of persons are called post-strata. A synthetic adjustment is performed in two steps. First, the preferred adjustment factors are estimated for 1392 post-strata. Then the adjusted estimate in each category for a census block is obtained by multiplying the unadjusted census count in that category by the adjustment factor. The adjusted census estimate for the census block is calculated by adding together the estimated adjustments for each post-strata represented in the block. Because of the problems of correcting a census with a survey, adjusted figures cannot be more accurate than the census counts in each of the 4,830,514 occupied blocks, or at all larger aggregations of them. There is no PES system—short of one which took a second perfect census—that could say adjusted counts are more accurate for all blocks. The question is whether the assumptions that underlie this synthetic

adjustment mechanism are good enough to conclude that the counts are sufficiently accurate to be usable at a block or precinct level.

As noted above, the synthetic adjustment process rests on the assumption that persons in each post-stratum are homogeneous with respect to their probability of being missed by the census, *i.e.*, their capture probability. This is admittedly a very difficult thing to measure. There were several approaches taken by the Census Bureau to validate the homogeneity assumption, all contained in project P12.

The first part of P12 collapsed the 1392 post-strata by age and sex into 116 larger groups. To test whether the people living on blocks within these 116 larger post-strata are homogeneous with respect to capture probability, the Census Bureau conducted an analysis of the homogeneity of 115 of the 116 larger post-strata (the 116th is persons living on Indian reservations). A regression model predicted an adjustment factor for block parts, then compared that with an adjustment factor of 1.0 (no adjustment) representing the numeric census counts. This predicted adjustment factor was also compared with the measured factor for the post-strata used in creating the adjusted counts. For 24 of the 115 post-strata the census count was superior while for 91 post-strata the adjusted count was superior in terms of numeric accuracy. The Director interprets these findings to "give support to the accuracy of the selected PES adjustment model." [80] Regrettably, this evidence does not directly address the homogeneity issue. Like the uncorrected loss function studies this simply compares the census and the PES to yet a third estimate (the regression equation) whose quality or closeness to truth is unknown. This cannot be called a test or even a verification of the homogeneity assumption. To pursue this approach, allowance should have been made for the true variance in the regression estimates in a manner analogous to that done in the Undercount Steering Committee Addendum for the target population. It must be understood that such errors can easily occur when cutting edge research is used for production purposes under extreme time pressure.

The second part of P12 analyzed the homogeneity of state parts within post strata. Techniques known as analysis of variance were used to determine the validity of using post-strata, rather than states, for estimation of adjustment factors. The study was designed to determine if there was relatively more homogeneity within state or within post-strata. The study showed that, with the exception of the Mid-Atlantic Division, state differences were not significant within post-strata. This result was compatible with the conclusion that there is relative homogeneity for state parts within post-strata. There is no evidence of homogeneity for other geographic levels.[81] The only conclusion that can be drawn from this study is that the Census Bureau was better off using the actual post-strata for synthetic estimation than using any state-specific effects. Whether the levels of homogeneity within post-strata are acceptable is not even addressed.

The third part P12 looked at state homogeneity from a different vantage point. It measured whether other factors that are often correlated with undercounting are homogeneous within post-strata. Contrary to the results of the second part of the studies, these factors showed significant heterogeneity by state within post-stratum for well over 80% of the post-stratum groups. This study went further and measured the homogeneity of some of the components of the dual-system estimates at the block level and found about 14% of the post-strata groups to have significant state effects. Thus, the evidence in this study for the presence or absence of homogeneity within post-strata is mixed.

In summary, the analysis presented for decision from P12 was substantially different from that planned by the Census Bureau and used only the State as a surrogate for heterogeneity. We clearly do not thoroughly understand whether or not heterogeneity is a real problem. There are indications that using post-strata for synthetic adjustment is better than using states, but nothing more. It is impossible to conclude from any information the Bureau has presented in P12 that there is not residual heterogeneity within post-strata.[82]

Project P15 approaches the homogeneity problem by attempting to measure the quality of the dual system estimates by examining their expected variability. The measure used to do this is called the coefficient of variation which is the ratio of the sample standard deviation to the sample mean. The PES was designed so that these coefficients of variation were expected to be equal to 0.7 percent for the areas used in the design. In fact, in 48 of the 54 areas examined, the actual coefficients of variation are larger than expected. They ranged from 0.45 percent to 4.4 percent. This is direct evidence of substantially more variability in the DSE than expected and indirect evidence of heterogeneity within post-strata.

Other arguments have been made about this guideline. As noted in the analysis of Guideline One, Ericksen, Estrada, Tukey, and Wolter rely heavily on the Wolter/Causey/Tukey argument that synthetic adjustment will increase the accuracy of the counts.[83] For the reasons explained in the discussion of Guideline One, I do not find this argument compelling. Its reliance on the unsubstantiated homogeneity assumption simply emphasizes the concerns raised earlier.

Estrada argues that it is not necessary to show that the adjusted counts have to be better for all purposes, if it is shown on average to improve counts for its principal uses. "Improved counts to meet Constitutional needs for reapportionment and redistricting would be sufficient justification to adjust, even though for some other uses adjusted counts are less valid." [84] I do not consider this argument persuasive. Reapportionment and redistricting counts are the most demanding in terms of accuracy because block level counts are required to accomplish both.[85] If adjusted counts are better for these purposes, then they would necessarily be better for all others.

McGehee asserts that "variances between processing offices and evaluation strata fall outside expected levels in a number of the evaluation studies. At the district office level and below the data contain such wide variances that they could not be reconciled without weighting them to

[80] Bryant, page 18.

[81] The Undercount Steering Committee report states that a majority of the Undercount Steering Committee believe this result would hold for other geographic levels. However, there is no evidence presented to support this. Undercount Steering Committee, page 2.

[82] Estrada agrees that the findings from P12 are mixed, although his conclusions differ from mine: "It supports the fact that PES poststrata are homogenous with respect to expected coverage error, but also questions the homogeneity of the division level poststratum. These findings lend support to the accuracy of the adjusted count based on the synthetic method particularly within poststrata and block-to-block variance in characteristics and net overcounts and undercounts. Overall, 79 percent of the time the adjusted count is better than the census count. Nonetheless, this research 'flags' the need to be aware of State effects." (Estrada, page 19.) Given the fact that reapportionment depends critically on state counts. Estrada's conclusions raise a large flag in terms of accuracy.

[83] See Estrada, page 19; Wolter pages 7–8; and Ericksen *et al.*, pages 20–21.

[84] Estrada, page 18.

[85] Recently, Mississippi's proposed redistricting plan was overturned by the Department of Justice for failure to use block-level data.

much higher levels." [86] As an example he notes that "the [matching] effectiveness rates varied from a low of 87.2% in Albany to a high of 93.49% in Kansas City. . . . [T]here was a significantly different level of success in Kansas City than in Albany. But why? The answer is that we do not really know." [87]

Special Advisory Panel Member Tarrance links the usability of adjusted counts for redistricting with the disruption the use of such counts would cause.[88] These arguments will be considered under Guideline Seven.

Wachter has serious concerns about the usability of these adjusted counts. I consider his concerns about state population totals and reapportionment under Guideline Three.[89] He does, however, present evidence that casts serious doubt on homogeneity within post-strata. Because "very little is known about local heterogeneity in census coverage," [90] he conducted simulations on 10 selected PES block clusters to determine the effect of an adjustment on both the improvement in the numeric level of the population at the district office level and the improvements in the shares or proportions of the population in a given district office. In other words, he considered both numeric and distributive accuracy. In Wachter's simulations, the level of the population is improved about twice as often as it is worsened by an adjustment. However, the shares suffer much more from the simulated adjustment. On average 59% of the office proportions are better, but the range over all the simulations shows anywhere between 39% to 78% improvements. Furthermore, in 7% of the simulation trials a majority of the districts are made worse. Now in any simulation, a true population for a block must also be simulated. Wachter argues that truth is chosen in his simulations so as to overestimate improvements achievable by an adjustment.

Wachter's evidence on heterogeneity is the only evidence that looks at actual behavior in the 1990 census and PES below the state level, and the only evidence that looks at the effect of heterogeneity on the shares of the population rather than the population levels. He states that his results are preliminary and need more work—but at least they are results that bear directly on the homogeneity issue. I find compelling his conclusion that "local heterogeneity is a serious problem for adjusting the 1990 census at district levels. My evidence indicates that a substantial portion, possibly a majority, of relative counts for district-size units can be made worse off by adjustment." [91]

Wachter made other efforts to measure block-to-block heterogeneity and district-to-district heterogeneity. These other attempts are inconclusive and neither support nor deny the homogeneity assumption, so, therefore, I did not consider them to weigh either for or against an adjustment.[92]

Heterogeneity and local variability pose a vexing problem for synthetic adjustment as GAO noted in their testimony.[93] In his article, Freedman makes this clear:

> Variability is a major obstacle to adjustment. Indeed, undercount rates differ from one geographical area to another, and from one demographic group to another. That is why synthetic estimates for small areas, based on demographic analysis, have not been widely accepted. However, adjustment by the DSE [Dual System Estimate] is unsatisfactory for the same reason. For example, one post-stratum consists of Hispanics—cross-classified by age, sex, and housing tenure—in central cities in the Pacific Division (California, Washington, Oregon, Alaska, and Hawaii). In round numbers, the 1990 population of the Pacific Division is about 40 million with 8 million Hispanics, 5 million of the latter being in southern California.
>
> Consider an adjustment for Stockton, a city of about 200,000 people in California's Central Valley, a 4-hour drive north of Los Angeles. The Hispanic population is about 50,000; there can be at most a few dozen Hispanics from Stockton in the PES [Post-enumeration survey], and a handful of gross omissions [persons counted in the "p" sample who were not in the "e" sample (census)] or erroneous enumerations [persons counted in the "e" sample (census) who were not found in the "p" sample]. No stable estimates could be developed from a sample that small. Instead, estimates for Stockton would be based on the adjustment factor for the whole post-stratum, the numbers being driven by PES data from southern California. The basic assumption: undercount rates for Hispanics are the same in Stockton as in Los Angeles. *There is no empirical evidence to support this assumption.* [Emphasis added.] And there is a similar problem for non-Hispanics. Indeed, adjustment factors for non-Hispanics in Stockton are driven by PES data on non-Hispanics in the whole Pacific Division. Apparently, Stockton's non-Hispanics are supposed to be like their counterparts in the north, while its Hispanics are taken to be southern. *Stockton is the rule not the exception.* [Emphasis added.] There are 39,000 state and local government areas to adjust; and only 5,000 sample blocks with PES data. *Most jurisdictions would be adjusted on the basis of data from elsewhere* [Emphasis added.]—and the synthetic assumption.[94]

None of the evidence I was given, other than Wachter's, confronted the measurement of this problem head on. The questions that remain unanswered are fundamental: What is the extent of residual heterogeneity within post-strata down to the county, city, precinct and block level, and what is the effect of that heterogeneity on the adjusted estimates both in levels and shares? Until this is known, the statement that the counts are usable for all census purposes is no more than an assertion.

Conclusions

I conclude that the considerations pointed to by Guideline Two tend to reject use of the adjusted figures and support use of the census counts. The adjusted figures—like the census counts—are consistent across all jurisdictional levels and of sufficient detail for all purposes. However, the adjusted figures do not appear to be of sufficient quality to be usable for reapportionment and redistricting. First, the distributive accuracy of the census counts is superior as concluded above in my review of the evidence on Guideline One. Furthermore, substantial evidence casts doubt on the homogeneity assumption underlying the entire synthetic adjustment methodology. Even if the tests discussed under Guideline One and based on the homogeneity assumption had proven favorable to adjustment, this evidence would weigh against adjustment. Instead, both considerations imply that the adjusted figures are not of sufficient quality to be usable for reapportionment and legislative redistricting. Thus, this Guideline weighs in favor of a decision not to adjust the census.

Guideline Three

The 1990 census may be adjusted if the estimates generated from the pre-specified procedures that will lead to an adjustment decision are shown to be more accurate than the census enumeration. In particular, these estimates must be shown to be robust to variations in reasonable alternatives to the production procedures, and to variations in the statistical models used to generate the adjusted figures.

[86] McGehee, page 32.

[87] McGehee, page 4.

[88] See appendix 3: Tarrance, V. Lance "Report to the Secretary of Commerce," Member, Special Advisory Panel, June 14, 1991, [hereafter Tarrance], pages 17–18.

[89] Wachter, pages 24–26.

[90] Wachter, page 26.

[91] Wachter, page 29.

[92] Wachter, pages 30–32.

[93] See the quotation from GAO in Guideline One.

[94] Freedman, pages 1233–1236.

Explanation

The Bureau of the Census will determine the technical and operational procedures necessary for an adjustment decision before the results of the post-enumeration survey are known. This procedure shall be chosen to yield the most accurate adjusted counts that pre-census knowledge and judgment can provide. The Bureau of the Census will then assess the components of systematic and random error in the procedure and it will assess the robustness of the estimates generated from that procedure. Various procedures and statistical models can be used to generate estimates of net overcounts or net undercounts and adjustment factors. This guideline specifies that a set of procedures for generating proposed adjusted counts will be determined in advance of receiving the 1990 post-enumeration-survey estimates. This guideline requires that these procedures be evaluated. These evaluations will identify other procedures and models that could be considered as reasonable alternatives to the chosen production process. These alternatives will be used to assess the accuracy and precision of the proposed adjusted counts. In addition they will be used to assess whether and by how much the adjusted counts could vary if alternative procedures were used.

Discussion

There are three questions raised by this guideline that have not already been dealt with in my conclusions about accuracy in the discussion of Guideline One:

(1) Were the procedures followed pre-specified?

(2) Were the estimates robust to production alternatives?

(3) Were the estimates robust to alternative statistical models?

Prespecification

The question of prespecification is difficult. No production of the complexity of the census or the PES can be completely prespecified. There are always unforeseen events that occur and that require modifications to the plan. In fact the procedures for the PES and for generating an adjusted count of the population were, broadly speaking, as prespecified. Even though there were several decisions, of some importance, made in the course of the estimation procedure, all were made solely by the career professional staff at the Census Bureau. The decisions reflected the best professional judgment of those career public officials vested with the responsibility for the census and the PES.

First, a decision was made not to combine DA with the PES to generate dual-system estimates. Second, there was a choice made of carrier variables to be used in the smoothing process. These variables help determine how the raw adjustment factors (published on April 18, 1991) are converted to the smoothed adjustment factors (published on June 13, 1991). Finally, in the smoothing process itself some observations which were either peculiar in their magnitude or their variance were treated specially. The Special Advisory Panel members were consulted in trying to deal with the difficulties encountered in the smoothing process.

Kruskal, Tarrance, and McGehee all raise concerns about the prespecification question. It is Kruskal's impression "that choice of the so-called smoothing procedures was profoundly based on PES results. One might indeed argue that such a choice has major merits, but it does not seem to me to follow the Guideline" [95] McGehee argues more strongly: "One's confidence is further eroded when—in an effort to explain unexpected results—the Bureau resorts to novel explanations, re-manipulation of the data, and a variety of other *ad hoc* techniques." [96] Tarrance expresses similar concerns: "Some procedures have been pre-specified but, as in all statistical operations, others have been suggested and/or adopted as the operations have been carried out. I have been concerned to note that a number of changes have been made in the last 18 months." [97] He also notes that "any attitude of 'if the numbers don't come out the way we think they should we can change plans' is diametrically opposed to what good government policy should allow. Furthermore, it is clear that the adjustment process is a statistical operation which has never been done before and there are many last-minute decisions being made." [98]

Ericksen, Estrada, and Tukey either find no problem with the prespecified procedures or do not mention it. Wolter notes that there were procedures in the enumeration that were changed late in the enumeration process that affected the PES; however, PES managers were able to cope with the changes in procedures. He also notes the decision not to combine the PES and DA and the smoothing decisions made during the PES process. He finds that each was treated with a high degree of professionalism.[99]

In any estimation process unforeseen difficulties will arise and no estimating system can be put on automatic pilot. The unsettling problem is that, as we will see below, the choices that occurred did make a difference in the outcome of the adjustment—differences large enough to change the implied apportionment of the Congress—and that different choices producing different results may have been made by other responsible individuals in the exercise of their best judgment. The enumeration process itself cannot be influenced in such a way. Any individual decision either has a tiny impact or is so distant from the final result (both in temporal terms and in statistical terms) that the decision maker does not know the import of his decision. This is simply not true of the types of decisions made here in the course of calculating PES count estimates. State counts were easily available to the persons deciding which smoothing method would be used. Although I believe that the decisions were made for sound professional reasons in the 1990 census, using these adjustment mechanisms opens the possibility for manipulation of future post enumeration surveys in ways that are unavailable in traditional census procedures. This weighs heavily against an adjustment of the census.

Robustness of the Results

I will combine the discussions of the robustness to alternative statistical methods and production methods in this section because they are for the most part intertwined.

One area in which statistical models could have an impact on the result of the PES is in the imputation of match status. As individuals from the PES are matched back to the census some cannot be definitively declared matched or unmatched, often due to missing data. The missing data were imputed to the unresolved cases and a match status was then assigned using a series of statistical models. The levels of missing data were sufficiently low that variation in these models made essentially no difference in the outcome of the PES (Studies P1 and P2). Here I concur with the Undercount Steering Committee judgment that the outcome is robust to the alternatives considered, although, as noted above, Wachter warns that unexamined assumptions underlie the statistical imputation models and, in

[95] Kruskal, page 4.
[96] McGehee, page 4.
[97] Tarrance, page 20.
[98] Tarrance, page 21.
[99] Wolter, page 9–10.

fact, the results could be sensitive to these assumptions.[100]

Wachter notes that the sensitivity of the imputation results to these unexamined assumptions, however, could have an impact on the apportionment of the House of Representatives that would be implied by an adjustment. He considers five alternative adjustment calculations: the smoothed estimates, the raw estimates, two of his imputation alternatives, and a fifth estimate that uses state adjustment factors based only on PES data gathered within that state. He finds that each method implies a different apportionment of the House, and eleven states either gain or lose a seat in at least one of the five alternatives. This instability in the results of the adjustment for the Constitutional purpose of the census argues strongly against an adjustment.[101]

The second area in which different methods could have affected the outcome is in poststratification. All the members of the same post-stratum receive the same adjustment factor. If post-strata are chosen differently then outcomes may be different. The Census Bureau investigated whether changes in the post-stratification by census division would change the results significantly by using an alternative post-stratification by state. This showed that three states would have had significantly different counts. It is also important to note that any variation due to uncertainty in post-stratification is not incorporated in the total error model.

A third area of concern is that of smoothing procedures. Smoothing is a technique that is used to remove some of the effects of random variability in the estimates of the adjustment factors for the 1392 post-strata, while preserving the meaningful systematic differences between subgroups. Since these adjustment factors are the results of a statistical process, they are subject to random variation. If you had taken a second sample the answer would be different. But some variation across the different poststrata is a result of real differences in behavior not simply random statistical variation. The point of the smoothing exercise is to remove the *random* variation while attempting to retain the real differences.

Smoothing involves three major judgmental decisions—the treatment of outliers, the variance pre-smoothing, and the choice of so-called carrier variables. We consider first the treatment of outliers. This is an extremely complex problem that posed great unforeseen difficulty for the Census Bureau. Let me start with a simple observation. When the final PES numbers were announced on June 13, 1991, a modified set of PES numbers was included as one of the alternatives considered as a possible set of final PES numbers but not selected. This set of numbers stood apart from the census and was closer to the selected method than the census. Thus it was a candidate for selection. This alternative, had it been chosen, would have implied a different apportionment of the Congress than the selected method. If the selected method were chosen and if the Congress were reapportioned on the basis of those numbers, California and Arizona would gain one more seat each and Pennsylvania and Wisconsin each would lose one seat compared to the census. Use of the modified PES estimates instead of the selected method would have resulted in a shift of only one seat—from Wisconsin to California. It is important to note that the only difference between the two methods is that, in the selected PES. 28 outlying variances out of 1392 variances were omitted from variance smoothing. In the modified version these 28 points were not omitted. Thus changing the treatment of only 2% of the points could have changed the allocation of one seat in the House of Representatives. I have included in Appendix 10 a list of State, county, and city populations under three smoothing schemes: the selected method, the modified method, and the raw adjustment without smoothing. Some of the sensitivities to smoothing choice are evident from these charts themselves. Let me highlight a few:

- The undercount rate for Arizona is estimated to be 2.8% under the modified PES smoothing scheme and 3.3% under the selected PES smoothing scheme.
- The undercount rate for Maryland is estimated to be 2.5% under the modified PES smoothing scheme and 1.8% under the selected PES smoothing scheme.[102]
- The undercount rate for the District of Columbia is estimated to be 5.6% under the modified PES and 5.0% under the selected PES smoothing scheme
- The undercount rate for Akron, Ohio, is estimated to be 2.2% under the modified smoothing scheme and 3.0% under the selected PES smoothing scheme.
- The undercount rate for Pasadena, Texas, is estimated to be 3.7% under the modified smoothing scheme and 3.0% under the selected PES smoothing scheme.
- The undercount rate for Miami, Florida, is estimated to be 5.4% under the modified smoothing scheme and 4.6% under the selected PES smoothing scheme.

The Census Bureau analysis emphasizes that the set of various population estimates derived from different smoothing methods are broadly similar in the counts they produce and, as a group, distinct from the census enumeration. I believe that, in fact, it would be difficult to choose on any objective statistical grounds among the host of alternatives the Census Bureau considered which do in fact produce different results for the Constitutional purposes of the census. As noted in the discussion of Guideline One, accuracy must be considered in terms of the distribution of the population not numeric accuracy. The Census Bureau analysis does not consider the similarity in terms of the population distribution of the sets of estimates or whether the variance inherent in those estimates, warrants the discarding of the census in favor of one of the particular estimates.

Wachter's analysis of the smoothing procedures that the Census Bureau used in developing the adjustment estimates also raises some serious concerns. He believes that "smoothing has turned out to be the most problematic part of the adjustment calculations," and that "the evidence leads me to fear that the smoothing has had more of an effect on the final adjustment than can be easily justified." [103]

As noted above, smoothing is a technique that is used to remove some of the effects of random variability in the estimates of the adjustment factors for the 1392 post-strata, while attempting to preserve the meaningful

[100] Wachter, pages 21–22.

[101] In connection with the loss function studies discussed in Guideline One, the Census Bureau compared the apportionment implied by the census to that implied by the so-called target population. They differed by two seats. The Bureau then considered 1000 random draws from the production DSE statistical distribution and compared the apportionment that would result from each draw to the target population apportionment. For 391 of the draws the production DSE apportionment did not differ from the target apportionment. For 567 of the draws there was a difference of one seat. For 42 there was a difference of two seats. This only shows that the PES estimator of apportionment differed from the target apportionment by 0.65 seats on average. It says nothing about the quality of the census, since the target is simply another adjusted estimate of the population, as the discussion of Guideline One demonstrates.

[102] If a state is estimated to have a greater than average (*i.e.*, 2.1%) undercount it gains proportionally from an adjustment. States below 2.1% lose. Thus the choice of adjustment method, had adjustment been used, would have determined whether Maryland was a winner or loser.

[103] Wachter, page 33 and page 34.

systematic differences. This is done using a technique called linear regression that "holds constant" attributes of the population we expect to be associated with low or high undercount rates in an attempt to isolate the random variation. The choice of the attributes to be "held constant"—also called carrier variables—is a matter of concern and will be discussed below. These regressions yield estimates of adjustment factors that supposedly have been purged of their random variability. Wachter characterizes these estimates as being "flattened." [104]

To calculate the smoothed factors one takes an average of the raw adjustment factor (before flattening) and the flattened adjustment factor—but a weighted, not a simple, average is used. For a particular post-strata, if you have observed a lot of random variability, the smoothed factor is chosen to be closer to the flattened factor—that is, the weight on the flattened factor is high and the weight on the raw factor is low. On the other hand, if the raw adjustment factor is fairly stable and does not show much random variation, you put more weight on the raw factor and less on the flattened factor when you calculate the smoothed factor. The smaller the random variation in a poststratum, the more the smoothed factor relies on the observed data and the less it relies on the regression estimate.

But there is another level of complication. The measures of random variation, called variances, are themselves subject to random variation and, as happened in this PES, the variances can be large and unruly. The variances themselves vary a lot. When there are large measured variances, the smoothed factors are closer to the flattened estimates and on the whole, you tend to get lower adjustment estimates. The Census Bureau decided to soften this effect by pre-smoothing the variances before smoothing the adjustment factors. So there are two levels of smoothing—first variances, then factors.

Wachter shows that "the effect of deciding to use pre-smoothed rather than unsmoothed variances is to raise many of the adjustment factors by several percentage points and raise some by more than six percentage points. The changes introduced into the adjustment factors are of the same order of magnitude as the sizes of the adjustment factors themselves. These are huge changes for a decision of detail." [105] The fact that the statistical artifice of variance smoothing is making substantial differences in adjustment factors is disturbing. As Wachter observes:

> The raw adjustment factors are at only one remove from the data, the PES fieldwork that is the real information we have. Assumptions go into their computation and they are subject to many kinds of random and systematic errors. Notwithstanding these limitations, there is a fairly direct link between people missed or miscounted somewhere in a sample block and a big or small raw adjustment factor. Smoothing the factors themselves involves operating at two removes from the data, importing more assumptions, but incorporating information about variability that comes ultimately out of fieldwork. Pre-smoothing the variances that go into smoothing the adjustment factors is at three removes from the data. It incorporates little, if any, further empirical information. It depends entirely on another set of assumptions.[106]

The fact that pre-smoothing makes so much difference reflects the irregular and variable nature of the PES data. The implication is that the assumptions underlying the statistical models being used are important determinants of the outcome of the adjustment calculation.

Wachter discusses at length the reasons for variance pre-smoothing, but one argument he made was particularly striking. The variance pre-smoothing essentially results in large variances being made smaller and small variances being enlarged slightly. This seems to be the opposite of what is desired. A large variance means that the adjustment factor is not well estimated—it is noisy—so when smoothing the factor you should put *more* weight on the so-called flattened factor. Decreasing the large variance means you put *less* weight on the so-called flattened factor. The opposite argument can be made for small variances. Therefore, variance pre-smoothing is arguably having a result exactly opposite from that intended by the smoothing process. In addition, because low adjustment factors tend to have small variances, pre-smoothing makes those variances higher and thus systematically discounts the evidence of low net undercounts.[107] In other words, presmoothing tends to artificially inflate already high undercount rates and artificially dampen already low undercount rates.[108]

Wachter cites three other problems with variance pre-smoothing: First, the variance smoothing is not directed at making covariances more accurate. In his view the motivation for presmoothing was heuristic. Second, there are no strong reasons for choosing among the many models available to actually smooth the variances. Third, the choice about variance pre-smoothing affects not only the adjustment factors but the total net adjustments for broad aggregates of the population. For example, the variance presmoothing changes the estimated net undercount in the West South Central region from 2.95% to 2.76%. In the East South Central, it changes from 2.43% to 2.68%.[109] Again, these are changes of a very significant magnitude given the size of the national net undercount.

The choice of carrier variables in the statistical regression procedures used to smooth the adjustment factors could have a significant impact on the outcome. The Special Advisory Panel commissioned a study by David Hoaglin to study this impact. This study is used extensively in the arguments of Ericksen, Estrada, Tukey, and Wolter. The conclusion was much the same as with the various treatment of outliers. The carrier variable choice made a difference, although in absolute numeric terms not a huge difference. The 13 models Hoaglin produces look roughly similar to each other and to the production PES estimates all of which are distinct from the census. The same is true if relative shares for the thirteen evaluation post-strata are computed—the various carrier variables produce results closer to the production PES estimates than to the census. No results are available at finer geographic levels (such as states, counties, or cities.)

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[104] Wachter, page 35.

[105] Wachter, page 36.

[106] Wachter, page 37.

[107] Wachter, page 39.

[108] In their letter submitted on July 11, 1991, Ericksen and Tukey dispute Wachter's concerns over variance pre-smoothing and contend that variance pre-smoothing helped the accuracy of the adjustment. In his rebuttal letter, submitted on July 12, 1991, Wachter stands by his statements. Both letters are contained in Appendix 16. It is difficult to referee this dispute in the eleventh hour, especially since the lateness of the Ericksen/Tukey letter gave little chance for Wachter to prepare a detailed response. In checking with the Census Bureau, I have found that, in fact, the pre-smoothing operation was agreed upon in advance, but in mid-May difficulties were encountered in that operation. The Census Bureau consulted with the panel and Tukey offered several remedies that Hoaglin and Glickman refer to as "prescriptions in the spirit of a mustard plaster . . . not a tightly specified procedure derived from established statistical theory." (Appendix E of Ericksen, *et al.*, page 15.) Although Hoaglin and Glickman, seem to indicate that the choice among the three remedies should not have much effect on the ultimate smoothed estimates, one of the three shows exactly the phenomenon that concerns Wachter, of raising high variances and lowering small ones. (See Appendix E of Ericksen *et al.*, page 22.) In fact, the choice of the "mustard plaster" did have an effect on apportionment (see main text above). Finally as Wachter points out, there is disagreement as to what constitutes a reasonable alternative.

[109] Wachter, page 39 and Table 3.1.

Wachter's assessment of the carrier variable selection is that "the effects of variable selection are not negligible but they are not a central issue." [110]

Ericksen points out that the total error model shows that the effects of the PES biases on population shares for the 13 large evaluation post-strata are small. In addition, he contends that his examination of the two estimates in the June 13, 1991, press release, shows the state population shares to be stable for the states that would gain or lose seats if the House of Representatives were reapportioned on the basis of adjusted counts. His reasoning is that the adjustments are larger than one or two times the standard error.[111] The difficulty with his reasoning is that it only considers sampling variability and ignores whether the shares are robust with respect to alternative statistical and production methods.

Conclusions

I have previously concluded that the adjusted figures have not been shown to be more accurate than the census enumeration. That is all that is required under Guideline Three to conclude that the census may not be adjusted. There are, however, additional considerations under Guideline Three under which I also conclude the 1990 census should not be adjusted.

It has proved virtually an impossible task to prespecify the adjustment procedure. It is equally impossible to prespecify the Census procedure. However, in the adjustment procedure an individual or responsible group must make choices which have politically significant effects on the counts that can be transparent to those making the choices. This puts the counts at greater risk of being manipulated than the census. There is no evidence of unprofessional or political manipulation in the 1990 PES program.

The results of the adjustment procedure are broadly robust at an aggregate, national level. However, although various alternatives seem to distribute counts in roughly similar ways, small changes in methodology can move seats in the House. It is also true that small changes in the census enumeration can move seats in the House as well, but no individual involved in the enumeration process can predict how. That is not true for the decisions for adjustment that cannot be or were not prespecified.

One of the most problematic parts of the adjusted process was the bundle of statistical techniques contained in the smoothing process. These techniques relied heavily on statistical assumptions, resulted in large changes in adjustment factors, and may very well have led to an overstatement of the undercount. Thus, this guideline weighs in favor of a decision not to adjust.

Guideline Four

The decision whether or not to adjust the 1990 census should take into account the effects such a decision might have on future census efforts.

Explanation

The Decennial Census is an integral part of our democratic process. Participation in the census must be encouraged. Respect for the objectivity, accuracy, and confidentiality of the census process must be maintained. Accordingly, if evidence suggests that adjustment would erode public confidence in the census or call into question the necessity of the population participating in future censuses, then that would weigh against adjustment.

On the other hand, if evidence suggests that the failure to adjust would erode public confidence in the census and thus result in widespread disinclination to participate in future censuses, that would argue for adjustment. The extent to which a non-adjustment would be perceived as a politically motivated act, and thus would undermine the integrity of the census, should also be weighed in making any adjustment decision.

Discussion

There is no scientific or quantitative means by which we can determine with reasonable certainty the impact of a decision made in 1991 on human behavior and activities that will occur in the year 2000 and beyond. Indeed, this guideline merely requires that we consider the effects that our decision today might have on future census efforts. In my view, such consideration requires that we examine relevant information and draw upon past Census Bureau experience as well as common sense in making rational predictions about such effects.

The universe of "future census efforts" encompasses a wide variety of activities: the efforts of individuals in completing census forms and cooperating with enumerators; the efforts of state and local officials, civic leaders and special interest groups in supporting outreach programs, public awareness campaigns, and active involvement in counting their target populations; the efforts of Census Bureau workers in enumerating as many households as possible; the efforts of Census Bureau professionals in making judgments and decisions about procedures to achieve the most accurate counts possible and to ensure objectivity and integrity of the process; and the efforts of the Department of Commerce, which includes the Census Bureau, to ensure appropriate levels of funding from Congress to support its enumeration activities. Each of these activities affects participation in and coverage of the census. To the extent that we can draw on relevant data, observations, and experience, consideration of the effects of decisions to adjust or not adjust on each of these activities is appropriate.

Sources relevant to our considerations include a study by the National Opinion Research Council (NORC), [112] public comments on the adjustment decision,[113] comments on Guideline Four submitted by the members of the Special Advisory Panel,[114] and discussions with experienced Census Bureau officials. Based on these sources, it is my conclusion that there is greater risk of potential harm to future census efforts as a result of a decision to adjust than as a result of a decision not to adjust. A discussion of the possible effects on each of these activities follows.

Effects on Individual Participation

Recently, the Census Bureau commissioned a study by the National Opinion Research Corporation (NORC) to try to measure how an adjustment might affect future census behavior by means of a telephone survey of a representative national sample of 2,478 households.

Persons were asked to evaluate the likelihood that they would participate in the next census. Then they were asked how that likelihood would change if there were an adjustment and how that likelihood would change if there were not an adjustment. The results were paradoxical—both a decision to adjust and a decision not to adjust would decrease the likelihood of participation.

The survey shows that the adjustment issue is not high in public consciousness or well understood. Only one-quarter (23.4 percent) of persons said they had seen or heard anything about the census in the past few months. When probed about what they had seen or heard, only 14.1 percent spontaneously mentioned anything to do with adjustment, undercount or errors in the census count. When told that people are talking about whether or not to adjust the

[110] Wachter, page 41.

[111] Ericksen, page 3.

[112] See Appendix 11. National Opinion Research Corporation, The Potential Impact of Adjusting of Not Adjusting the 1990 Census, June 19, 1991.

[113] See summary of comments on Guideline Four in Appendix 8.

[114] Ericksen, page 3; Estrada, page 20; Kruskal page 4; McGehee, page 33; Tarrance page 23; Tukey, page 2; and Wachter, page 42.

results of the census to correct for errors in counting the population, 22.3 percent then recalled they had seen or heard something about this. Probing questions showed that only 4.9 percent understand the adjustment issue.

Prior to any discussion of adjustment, a total of 84 percent of those surveyed stated they were "extremely or very likely to participate" in the next census. After the discussion of adjustment, 75.5% were "extremely or very likely to participate" in the future if the census were adjusted, as compared to 71.3% if it were not. Thus, while these results indicate that intention to participate in future censuses is marginally higher if the census were adjusted than if it were not, there is less inclination to participate in the future regardless of the outcome of the decision. As NORC points out in its conclusions: "While large numbers remain very favorably disposed to participating in the next and future censuses, this intention is a very slippery, ephemeral and changeable one . . . subject to influence by factors like the adjustment decision or, more likely, from the controversy or fallout emanating from the events that follow that decision." The survey also indicates that, prior to any discussion of adjustment, 5.5 percent were "not very likely" to participate in the next census. A decision to adjust would result in 5.3 percent in the "not very likely" category. A decision not to adjust would result in 8.6 percent in this category.

It is unclear what this survey meaningfully demonstrates, other than confusion over what an adjustment is and the negative effect of the controversy over adjustment on the present perception of a person's likelihood of participation in future censuses. However, as the survey report emphasizes, the need to explain the issue of adjustment and its implications will necessarily outlive the survey and the adjustment decision itself, and the inability of the surveyors to explain the issues to those surveyed is certainly grounds for some caution.

The division of public opinion on the future effects of adjustment indicated by this survey is consistent with the division of opinion demonstrated by the public comments received by the Department. While some claimed that an adjustment would erode public confidence in the census and thus lower future participation, others claimed that a decision not to adjust would erode public confidence and thus lower future participation.

The explanation of this Guideline states that evidence of widespread disinclination to participate in future censuses as a result of a decision not to adjust would weigh in favor of an adjustment. Neither the public comments nor the NORC survey provide evidence that this will occur. Indeed, the NORC study indicates that a decision not to adjust would make only 8.6 percent "not very likely" to participate in the future, just 3.1 percent more than those who would be "not very likely" to participate in any event. Thus, while there would be some additional disinclination to participate, it would not be widespread.

The explanation of this Guideline also states that evidence that calls into question the necessity of the population participating in future censuses would weigh against an adjustment. A number of the public comments express concern that an adjustment would result in the perception that an individual's failure to participate would be compensated by an adjustment and thus lower participation. In light of this, I am skeptical rather than optimistic about the likely motivation of individuals to participate in the future if an adjustment were made. However, I do not find compelling evidence in either direction regarding the effects of a decision on future individual motivations.

Effects on Complete Count Efforts by State, Local, Civic, and Interest Group Leaders

A number of the public commentators, as well as Wachter [115] and Tarrance,[116] expressed serious concerns that an adjustment would negatively affect the efforts by state, community, civic, and interest group leaders who traditionally provide essential support in encouraging participation in the census. I share these concerns. Currently, it is in the interests of every governor, mayor, and interest group to help get their target populations counted. The Census Bureau works closely with such officials and groups for two to three years before census day. The efforts include mapping, address compilation, massive advertising campaigns, and public awareness activities. I agree with my advisors who believe that such cooperative efforts are absolutely critical to the Census Bureau's mission to conduct an actual enumeration of all persons residing in the United States on census day, and particularly critical in reaching the hardest to count. Like others, I am concerned that an adjustment will remove the incentive that these public officials and groups currently have to provide active support in achieving a complete count.

Based on the public comments, it is clear that many public officials believe that an adjustment will correct specific errors they have identified in the count of their communities. With such mistaken impressions, it is unrealistic to expect these leaders to put census outreach efforts above the many other claims on their limited resources. As Wachter predicts, complete count committees, local advertising, celebrity appearances, and special programs to ensure more complete minority counts would be likely to suffer as a result of an adjustment.[117]

Senior officials at the Bureau, including the Director, agree with this assessment. At the same time, the Director believes that states and cities will still have an incentive to encourage participation in order to get the best possible city planning data. I find this unpersuasive in light of the numerous public comments received from local officials demonstrating a profound lack of understanding of the effects of an adjustment and a misplaced faith in its ability to correct particular problems they have identified in their communities.

I find no evidence indicating that local support would decrease as a result of a decision not to adjust the census.

Effects on Funding of Future Censuses

Tarrance [118] and Wachter [119] expressed concern that an adjustment would adversely affect the Department's ability to obtain sufficient funding for future censuses. I share this concern. The most expensive element of the census is the extraordinary effort to count the last five percent. With the illusory prospect of an adjustment to achieve a full count in congressional districts and states, it would simply be unrealistic to expect Congress to appropriate funds to the full extent necessary to complete an enumeration of the hard to count. Without the funds needed to complete an enumeration, the quality of census data, especially in smaller areas, would be jeopardized. There appears to be little risk that Congress would deny such funds as a result of a decision not to adjust.

Effects on Efforts by Census Enumerators

As Wachter recognized, the future effects of a decision to adjust could be most severe on those temporary workers who must actually conduct the enumeration process.[120] The difficulties

[115] Wachter, page 42.
[116] Tarrance, page 23.
[117] Wachter, page 42.
[118] Tarrance, page 23.
[119] Wachter, pages 42–43.
[120] Wachter, page 43.

of hiring, training, and supervising the thousands of temporary census employees are well-known and well-documented. It is time-consuming, often tedious, and occasionally dangerous work that requires extraordinary diligence for less than commensurate pay. There is a real risk that, with an expectation of a correction through adjustment, the field staff would not have the same sense of commitment and public mission in future censuses and, as a result, careless and incomplete work would increase, thereby decreasing the quality of census data. These are the workers the Bureau depends on to collect the data from the groups that are hardest to enumerate. If these data suffer, the information lost at the margin is information that is especially important to policy development.

I am unaware of any concerns that census enumerators would be less motivated as a result of a decision not to adjust the census.

Effects on the Independence of Bureau Professionals and the Integrity of the Census

Senior Bureau officials as well as Tarrance [121], Wachter [122], and McGehee [123] have raised concerns about the potential for manipulation of an adjustment for partisan purposes. As Wachter recognized, adjustment may pose significant risk to the technical independence of Census Bureau professionals who have traditionally been free from external influence in the implementation of their mission. [124] A principal drawback of adjustment is the fact that a few technical decisions can swing the outcomes of apportionment, redistricting, and Federal funding allocation. Decisions that may be nearly equally defensible from a technical standpoint may have very different outcomes which can be known in advance of the decisions. Thus, adjustment opens the door to manipulation of the census for partisan gain. It would therefore greatly increase not only external scrutiny and second-guessing of Census Bureau professionals and prospective candidates for key technical positions, but also inevitably increase pressure to politicize these positions. This would impose an even greater burden on technical staff in their attempts to make scrupulously objective and fair decisions. These risks pose serious threats to the integrity and objectivity of future censuses.

[121] Tarrance, page 5.
[122] Wachter, page 44.
[123] McGehee, page 33
[124] Wachter, page 44.

Concerns have also been expressed in the public comments and by Wolter [125] that a decision not to adjust the census may be seen as politically motivated and therefore adversely affect the integrity of the census. While I recognize these concerns, I believe they are outweighed by the likely adverse effects on future census efforts from an adjustment.

Conclusion

Based on the information available, I conclude that an adjustment would adversely affect future census efforts to a greater extent than any adverse effects of a decision not to adjust. The evidence indicates that the controversy over adjustment is likely to have a negative effect on future censuses regardless of the outcome of the adjustment decision. I am concerned that an adjustment would reduce state and local support for future censuses, adversely affect the Department's ability to obtain appropriate funding for future censuses, adversely affect the quality of the work done in the future by temporary census enumerators who are essential in reaching the hard-to-count, subject the Census Bureau to partisan pressures, and create the possibility for political manipulation of future census counts. Thus, this guideline weighs in favor of a decision not to adjust.

Guideline Five

Any adjustment of the 1990 Census may not violate the United States Constitution or Federal statutes.

If an adjustment would violate Article I, Section 2, Clause 3 of the U.S. Constitution, as amended by Amendment 14, section 2, or 13 U.S.C. section 195, or any other constitutional provision, statute or later enacted legislation, it cannot be carried out.

Discussion

In addition to the technical and operational aspects of the census and the proposed adjustment which I have considered in connection with Guidelines One through Four, I have also considered the constitutional and statutory implications of an adjustment decision. In my view, neither the Constitution nor the relevant statutory provisions are themselves conclusive as to whether the proposed adjustment would be unconstitutional or unlawful because the *sine qua nons* of constitutionality and lawfulness and the propriety of adjustment are the same: the need for unambiguous accuracy of the adjustment methodology and data. Because analysis of the significant legal issues is thus dependent upon the statistical analysis, which itself mandated my decision on the substantive merits not to adjust, it was unnecessary to decide the legal issues. This Guideline therefore only served to verify, not determine, my decision.

[125] Wolter, page 11.

Constitutional Considerations

While not free from doubt, it appears that the Constitution might permit a statistical adjustment, but only if it would assure an accurate population count. See *Carey* v. *Klutznick*, 508 F. Supp. 404 (S.D.N.Y. 1980); *Young* v. *Klutznick*, 497 F. Supp. 1318 (E.D. MI 1980). By implication, then, a determination that the proposed adjustment would not discernably or reliably improve the accuracy of the headcount would raise uncompromisable constitutional concerns, inasmuch as adjustment would not be contributing to the most accurate count, but rather would be injecting additional uncertainty and error. Thus, while the Constitution might not, *per se*, bar an adjustment, the question of whether a particular adjustment is constitutionally valid can only be made after the final form of the adjustment is known.

This principle—that an adjustment must be consistent with the constitutional requirement of "enumeration," i.e., an accurate count free from politicization and equivocation—is also supported by the intent of the Framers that the census utilize verifiable methods which obtain an accurate population count. This goal of accuracy would not be met, to give the clearest example, by mere guesswork. The central question under the Constitution thus supports, though it did not determine, my conclusion; the need for verifiable methodology and unambiguous data are the modern-day requisites of what was explicitly desired by the Framers when they provided for an "actual Enumeration." That phrase commands for all time that what shaped the details of the very first congressional apportionment (there was then as yet no census)—guesswork and political deal-making—never would be permitted again.

As the discussion of Guideline One demonstrates, the evidence of improved accuracy resulting from the proffered adjustment methodology is at best mixed. That evidence is not sufficient as a matter of substantive merit and, derivatively, it also fails the test prescribed under the Constitution. While the essence of my decision not to adjust rests in the uncertainty of the proposed adjustment and the questionable nature

of the data produced, that very uncertainty and question mark the rough shoals of politicization that the framers mandated be avoided when they required "enumeration," that is, an objectively accurate count.

Census Act Provisions

The Census Act contains two provisions authorizing the Secretary of Commerce to use sampling to conduct the decennial census. See 13 U.S.C. section 141(a) and 13 U.S.C. section 195.

Section 141(a) provides in pertinent part:

> The Secretary shall, in the year 1980 and every 10 years thereafter, take a decennial census of population as of the first day of April of such year, which date shall be known as the "decennial census date", in such form and content as he may determine, *including the use of sampling procedures and special surveys.* (Emphasis added.)

Section 195 provides:

> *Except for the determination of population for purposes of apportionment of Representatives in Congress among the several States,* the Secretary shall, if he considers it feasible, authorize the use of the statistical method known as "sampling" in carrying out the provisions of this title (Emphasis added.)

While judicial opinion is unsettled on the question of whether adjustment violates section 195, the majority of courts considering this issue have ruled that section 195 permits an adjustment if the adjustment method makes the census more accurate. See *Cuomo* v. *Baldrige,* 674 F. Supp. 1089 (S.D.N.Y. 1980), *Carey* v. *Klutznick,* 508 F. Supp. 404, at 415 (S.D.N.Y. 1980); see also, *City of Philadelphia* v. *Klutznick* 503 F. Supp. 663 at 679 (E.D. PA 1980); *City of New York et al.* v. *United States Department of Commerce. et al.,* (S.D.N.Y. 1990). *But see Orr, et al.* v. *Baldrige, et al.,* U.S.D.C., S.D. Ind., No. IP 81-604-C, July 1, 1985. Even assuming that the statute does not *per se* prohibit an adjustment, not all forms of adjustment would be sanctioned and the legality of the adjustment could only be determined after the form of adjustment is chosen. Thus, as with the constitutional issues, the analysis of the statutory issues cannot be separated from the analysis of the accuracy of the chosen adjustment method. Because the evidence of improved accuracy from an adjustment is insufficient, the standard articulated by the majority of these courts is not met. While this legal conclusion was not dispositive, it affirms my decision not to adjust based on the substantive merits.

Conclusior

The question whether the chosen method of adjustment would violate the Constitution and federal statutes depends upon the substantive analysis of whether accuracy of the census is improved by an adjustment. Because there are other compelling substantive reasons not to adjust, legal considerations did not provide a basis for my decision.

Guideline Six

There will be a determination whether to adjust the 1990 census when sufficient data are available, and when analysis of the data is complete enough to make such a determination. If sufficient data and analysis of the data are not available in time to publish adjusted counts by July 15, 1991, a determination will be made not to adjust the 1990 census.

Explanation

It is inappropriate to decide to adjust without sufficient data and analysis. The Bureau will make every effort to ensure that such data are available and that their analysis is complete in time for the Secretary to decide to adjust and to publish adjusted data at the earliest practicable date and, in all events, not later than July 15, 1991, as agreed to in the stipulation. Note, however, that the Department and the Bureau have consistently stated that this is the earliest possible date by which there is a 50 percent chance that an analysis could be completed on which a decision to adjust could be based. If, however, sufficient data and analysis of the data are not available in time, a determination will be made not to adjust the 1990 Census. The coverage evaluation research program will continue until all technical operations and evaluation studies are completed. Any decisions whether to adjust other data series will be made after completion of those operations.

Discussion

In order to evaluate the quality of the census and the post-enumeration survey, the Census Bureau conducted an extensive and ambitious research program designed to provide timely information on which to base a decision by July 15, 1991. Due in part to some unexpected anomalies in the data, progress on the evaluation was delayed in the final critical weeks, leaving the Bureau little time to complete its analyses. These pressures may have affected the quality of the research, and there is still much that we do not know about the quality of the PES and the adjusted counts relative to the enumeration. Nonetheless, based on the record available, I believe there is sufficient evidence to make a decision on adjustment.

The Census Bureau has done a remarkable job of condensing into a few short months a challenging evaluation program that was comparable to a multi-year research program for the 1980 census and the 1987 test of adjustment-related operations. The Census Bureau produced highly technical research on a very tight production schedule, using tools that were on the cutting edge of statistical theory and survey methods. The dedication, professionalism and hard work of Census Bureau staff under often intense pressure is truly commendable.

Although sufficient data are available for me to decide the adjustment question, it is important to note that because of the court imposed deadline for the decision, the analyses of the data are far from compete. All parties involved in the decision making process have expressed a desire for more time to digest and analyze the voluminous material created by the research program. I am particularly concerned about problems in data quality and analysis that were revealed, or occurred, in the final weeks before the decision.

Good research requires a careful weighing of the evidence, especially when it is on the frontier of the science. When such novel research is to be used for such far-reaching policy purposes, it requires discussion with peers who have not been intimately involved with the details so that some perspective can be gained. It benefits from probing questions, from looking at the data from different perspectives, from the use of alternative models and from intense and independent professional scrutiny. The time schedule simply did not permit a full range of such activities.[126]

Before the release of the selected and modified PES numbers, an inconsistency was found in the calculation of the margins of error upon reviewing the proposed release in its penultimate form. This was not a subtle error, but one that should have been caught by a careful cross-checking of the tables. After being informed of the inconsistency, the Census Bureau began work to discover its source. Fortunately, no fundamental error had been made. However, the release was delayed by almost two weeks, setting back an already tight schedule in the last critical weeks of evaluation. Such errors were the result of too much work being compressed into too little time. To its credit the Census Bureau worked hard

[126] Kruskal makes a similar point (Kruskal, page 6) as does Tarrance (Tarrance, page 27).

to find the error, fix it, and ensure that accurate data were released.

Later, in reviewing the work of the Undercount Steering Committee, fundamental questions were raised about measurement of the relative accuracy of the census and the PES. The loss function analysis was found to be unconvincing. The Census Bureau was therefore asked to revisit parts of its work. As a result of these questions, the Bureau staff found an error in the calculation of the loss functions. Correction of this error changed the number of States for which the census counts were judged more accurate than the adjusted figures from 11 to 21—a substantial and significant increase.[127]

An Addendum to the Undercount Steering Committee report was filed on Thursday, June 27, 1991. In section 4 of that addendum, which is included as appendix 5, the Undercount Steering Committee states the following:

> Given this new information, the Undercount Steering Committee members reevaluated their positions regarding the report issued on June 21, 1991 * * *
>
> The new information added uncertainty to the decisions of the majority, but their overall conclusions were not changed. In addition, particular sections of the report present representations of committee opinions that are now weakened by the new information. The sections of the report most affected by these new data are:
>
> The statement on page 6 of the report that 39 of 50 States are made more accurate by adjustment would be changed under the new loss function analysis; and
>
> Page 4 of the report summarizes the conclusions of the committee regarding Guideline One. The summary indicates that the majority of the committee relied on the loss function analysis that showed that a large majority of areas were made more accurate by adjustment. This is a stronger statement than the position now held by many of the committee members.
>
> In conclusion the overall committee position has not changed regarding adjustment, but has been weakened somewhat. These new data also underscore the points raised in report's findings on guideline 6 (see p. 12–13). When additional information, as the data presented above, becomes available, the committee acknowledges that it may strengthen or weaken its conclusions. On June 21 the committee judged that further analysis would be unlikely to change its conclusion. The majority stands by its original conclusion while acknowledging that the ongoing work, had it been available by the date our recommendation was due, may have caused different "weighing" of the results.[128]

These eleventh-hour findings weakened a key piece of evidence favoring adjustment. Because of these two significant errors, my concerns about the sufficiency of data and the strength of analysis supporting adjustment were heightened.

A second example of the pressures of the schedule is that as of the afternoon of Thursday, July 11, 1991, just two working days before my decision would have to be announced, I received a communication from Ericksen and Tukey taking issue with some of the conclusions in Wachter's report. Although I understand that many of the issues surrounding adjustment will be debated for a long time to come, the fact that some of the members of the Special Advisory Panel feel it incumbent upon themselves to offer last minute advice reinforces my perception that a full professional airing of issues has not taken place. Wachter wrote a speedy response to Ericksen and Tukey which I received on Friday, July 12, 1991. But a last minute debate by letter is not the way to carry out the important dialogue required on these issues.[129]

Over the course of the next months and years the data will be studied, the models tested, the professional discussions joined. We do not know what will be discovered about the quality of the PES data and the models that led to the adjusted counts. I am sure that the Census Bureau will not compromise its richly-deserved reputation for thorough and careful research. We need those efforts to build toward a better census in the year 2000.

But the question is whether we should adjust the census based on the data and incomplete analysis that we have now. As Wachter notes, we must "strike a sensible balance between the need to reach closure and the need to check and study further." [130] The decision must be made on its merits.

Notwithstanding my concerns about the effect the July 15, 1991, deadline had on research efforts, I conclude that sufficient data exist to permit me to decide whether to adjust the census. I conclude that the data support a decision not to adjust. Among the facts that weigh against an adjustment are:

- The PES missed a significant number of persons whom we cannot locate. Thus we cannot judge whether the adjusted census is distributionally superior to the enumeration simply by putting back into the count those we can locate by the PES.
- At the most aggregate level, the PES would move the count of the population in the opposite direction for some demographic groups as compared to those implied by DA.
- There is no convincing evidence to suggest that the adjusted counts give a more accurate count of the distribution of the population across various levels of geography. In fact the evidence indicates the census counts probably yield a more accurate measure of the distribution of the population.
- There is no convincing evidence that homogeneity within the poststrata used in adjusting the census counts is a statistically valid assumption.
- There is evidence that the estimates of the population produced by adjusting the counts are sensitive to small changes in the estimation procedure and these have significant effects.

Thus I find that the evidence presented is sufficient to conclude that the counts should not be adjusted.

Conclusion

An adjustment to the census is a fundamental change in the way we count and locate the persons residing in the United States. I am deeply concerned that if an adjustment is made, it would be made on the basis of research conclusions that may very well be reversed in the next several months. That would be bad for the country and bad for the Census Bureau.

The results of the PES evaluation studies are not yet completely analyzed. Because of the compressed time schedule imposed by the July 15 deadline, the analysis has not been subject to the full professional scrutiny that such important research requires and deserves. To the Census Bureau's great credit, the statistical tools used to calculate and evaluate the adjusted counts are at the cutting edge of statistical research. But such cutting edge research is not tried and true—it requires more thorough scrutiny before it can be used to affect the allocation of political representation and Federal funding.

Nonetheless, the demands of good research must be weighed against the need for a timely decision. In time we may find a way of combining the PES and the census to create counts that better reflect the absolute levels and the distribution of the population. There are sufficient data and analysis to support a decision not to adjust.

Guideline Seven

The decision whether or not to adjust the 1990 Census shall take into account the potential disruption of the process of the orderly transfer of political

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[127] As noted in Guideline One, these numbers are for the version of the analysis in which it is assumed that the measured variance is the whole story. As discussed there, the change is even more dramatic (from 11 to 29) if the true variance is assumed to be twice the measured variance.

[128] Addendum, page 6–7.

[129] Both letters are contained in Appendix 16.

[130] Wachter, page 46.

representation likely to be caused by either course of action.

Explanation

This guideline is intended to ensure that the factor of disruption of the process of the orderly transfer of political representation is explicitly taken into account as the decision is reached. For example, many states have pointed to adjustment as being disruptive to their redistricting plans. Likewise, members of some communities that are believed to have been historically undercounted contend that if the Census were not adjusted, this would disrupt the orderly and proper transfer of political representation to their communities. The inability to ensure accuracy of counts at local levels may result in politically disruptive challenges by localities to official census counts.

This guideline recognizes that the Decennial Census plays a pivotal role in the orderly redistribution of political representation in our democratic republic. The process used to generate the required counts must not be arbitrary either in fact or appearance. The Secretary is thus obliged to consider the impact of his decision on the fairness and reasonableness of that redistribution to all those affected. This guideline requires an explicit statement of how and to what degree adjustment or non-adjustment would be disruptive. Even though these are concepts that are not easily quantifiable, they warrant serious consideration in order for the Secretary to make a prudent decision on an issue that profoundly affects public policy.

Discussion

Among the primary purposes of the census are to provide the basis for the reapportionment of the House of Representatives and the drawing of new Congressional district lines within states. Census figures are also used by most states to redraw state legislative district boundaries, as well as by cities and counties in redrawing their own districts.

The Clerk of the U.S. House of Representatives has officially certified to each of the fifty states the number of seats allotted to the state for the 103rd Congress based on the census figures released on December 26, 1990. As of May 1991, some 20 States had already enacted either or both of their Congressional and State legislative redistricting plans. The U.S. Department of Justice is reviewing approximately one dozen of the state plans as well as those of many cities and counties to ensure compliance with the requirements of the Voting Rights Act.[131]

If adjusted census counts were issued, Congress would have to decide whether to change the apportionment for the 103rd Congress which is to be elected in November 1992. If there were a decision to change the apportionment using the formula in current law, the Clerk would have to issue new certificates to the states advising them of the number of seats to which they would be entitled based on adjusted counts. If this change were made, the States of California and Arizona would gain one seat each and the States of Wisconsin and Pennsylvania would each lose one seat relative to the apportionment previously certified by the Clerk of the House.

It is unclear whether Congress would change the apportionment even if adjusted counts were chosen. The requirements of the statutes governing apportionment were fully met in January with the certification of the number of seats to each state. Thus, as noted in a number of public comments [132], additional action may be required on the part of Congress to change that apportionment. Whether, how, and when that action would be taken is for the Congress to determine.

It is important to remember, however, that the modern apportionment process was designed to be automatic. Once the counts were transmitted by the President to the Congress, the apportionment took place without legislative action. This design was intended to put an end to the blistering fights over apportionment that occupied earlier Congresses and, in fact, prevented reapportionment after the 1920 census, depriving citizens of a fair allocation of political representation throughout the nation for the remainder of the decade.[133] The adjustment of the Census might well create similar bitter disputes and paralyzing legal challenges over the apportionment of the 103rd Congress. The political implications of this are matters of substantial concern.

If the adjusted census were the basis for a reapportionment of the House, for the first time, the apportionment would not be determined solely on the basis of the number of persons within each State's border. This is due to the effects of cross-state groupings of post-strata in the PES on the adjustment process. For example, if the counts were adjusted, the certified population count for Delaware would depend on the results of the PES in Maryland, the District of Columbia, West Virginia, Virginia, North Carolina, South Carolina, Georgia and Florida. This is because Delaware is in the South Atlantic census division, and PES estimates are developed division-wide.

At the State level there is also likely to be confusion, disruption and extended litigation if the census figures are adjusted. Members of the Special Advisory Panel reported on extensive testimony they received from members of the National Conference of State Legislators in Baltimore, Maryland on June 28, 1990.[134] The testimony focused on the effects of an adjustment on the states' ability to accomplish redistricting in compliance with state-imposed legal deadlines. Witnesses were concerned that the electoral process would be paralyzed by the endless litigation which two sets of census numbers would be certain to provoke. Witnesses cited major problems with adjustment: costs and delays in drawing new plans, costs of additional elections, the need for costly special legislative sessions, time constraints, and charges of partisan tampering with census data. Based on the testimony, it is clear that adjustment would create serious disruption for at least a dozen states that have early redistricting schedules or constitutional deadlines. Some states have simply delayed starting the process until after the adjustment decision. As Estrada recognized, adjustment also would require modification of recently designed districts to meet one-person, one-vote requirements.[135]

Protracted legal battles that preclude redistricting in time for the 1992 elections would deprive minority groups and others the opportunity to realize and benefit from the gains achieved through demographic shifts during the past decade. The same pattern would likely occur in redistricting efforts for city and county elections, which have already begun in a number of areas. Moreover, the adverse effects of an adjustment on the accuracy of small area counts (as demonstrated in the discussions of Guidelines One through Three) would likely result in politically disruptive challenges by localities to adjusted counts.

Several public commentators, as well as Tukey,[136] noted that such disruption

[131] See appendix 12. Turner, Marshall, "Planning the 1990 Census Redistricting Data Programs," U.S. Bureau of the Census, [hereafter Turner].

[132] See the summary of public comments on Guideline Seven in appendix 8.

[133] See the discussion of this matter in Chapter Six of Margo J. Anderson, The American Census: A Social History. New Haven and London: Yale University Press. 1988.

[134] Tarrance, page 28 and Wachter, page 47.

[135] Estrada, page 23.

[136] Tukey, page 2.

was foreseeable at the time of the Department's decision to consider an adjustment and that anticipated effects should not be considered in making the decision. The fact that disruption could be anticipated does not mean that it should be ignored. Indeed, consideration of disruption as a factor to be weighed in the decision was legally upheld. Moreover, as Tarrance stated, "we would not be responsible stewards of the public trust if we do not understand that we are considering more than just a scientific statistical improvement of an imperfect government program." [137] Because the census is the basis for allocating political representation in our country, the public policy implications of adjustment, including resulting political disruption, had to be considered in reaching this decision.

The potential for disruption as a result of an adjustment must be weighed against any disruption that would occur from a decision not to adjust. There will inevitably be litigation resulting from a decision not to adjust that may also delay or disrupt redistricting. Some public commentators claim that the unadjusted census is itself disruptive because it does not ensure certain groups of their rightful claims on political representation and Federal funding. These claims rely fundamentally on the conclusion that the adjusted counts better reflect the distribution of the population. As explained in the discussions of Guidelines One, Two and Three, the evidence supports the contrary conclusion.

Estrada asserted that the public good is better served by focusing on the potential benefits to millions of persons rather than on the limited number of Congresspersons and state legislators who would be affected by a decision to adjust.[138] As demonstrated previously, the evidence indicates that millions of Americans may be harmed rather than benefit from an adjustment. Moreover, we must remember that the Congresspersons and state legislators who would be affected by an adjustment are elected by and represent millions of Americans in the political process.

Comments by members of the public and by Estrada [139] noted that an adjustment would result in more equitable allocations of federal funding to states and cities, a consideration which in their view must be weighed against any disruptive consequences from adjustment. Again, this claim assumes that the adjustment provides a more accurate distribution of the population across states and localities, an assumption which is not warranted by the evidence.

Moreover, it has been demonstrated that an adjustment of the census would have very little effect on the distribution of Federal funds. The study in Appendix 15 [140] shows that less than one fifth of one percent of Federal funds would be reallocated as the result of an adjustment. Twenty-one or fewer states would receive additional funds from an adjustment. Fewer than half of all jurisdictions would be allocated additional funds as the result of an adjustment. As the study demonstrates, those jurisdictions that do benefit would receive on average only $56 in additional funds per "adjusted" person.

Thus, even if the claim that an adjustment would more accurately (and thus fairly) allocate federal funds were valid, the adjustment would not result in significant shifts of those funds.

Conclusion

Any decision will result in some level of disruption through legal challenges. On balance, the record indicates that a decision to adjust would likely be more disruptive than a decision not to adjust. A decision to adjust would clearly cause disruption in those States that have early redistricting deadlines. The assertion that persons are denied their rightful claims without an adjustment assumes that the distribution of the population is improved by an adjustment. Based on the evidence, this assumption is invalid. Thus, this guideline weighs in favor of a decision not to adjust.

Guideline Eight

The ability to articulate clearly the basis and implications of the decision whether or not to adjust shall be a factor in the decision. The general rationale for the decision will be clearly stated. The technical documentation lying behind the decision shall be in keeping with professional standards of the statistical community.

Explanation

It is the responsibility of the government to have its critical decisions understood by its citizens. We recognize, however, that the degree to which a decision can be understood cannot alone dictate an important policy decision.

The decennial census is a public ceremony in which all usual residents of the United States are required to participate. If the census count were statistically adjusted, the rationale for that action must be clearly stated and should be understandable to the general public. If the decision were made not to adjust, the elements of that decision must also be clearly stated in an understandable way. It will be the responsibility of the Department of Commerce and the Bureau of the Census to articulate the general rationale and implications of the decision in a way that is understandable to the general public.

This does not require the Bureau or the Department to explain in detail to the general public the complex statistical operations or inferences that could lead to a decision to adjust. But, as with any significant change in statistical policy, the government has the duty to explain to the public, in terms that most can understand, the reason for the change. If the decision is not to adjust, (that is not to change) the public will be informed as well.

The last part of the guideline ensures that the methods, assumptions, computer programs, and data used to prepare population estimates and adjustment factors will be fully documented.

The documentation will be sufficiently complete for an independent reviewer to reproduce the estimates. These standards apply to the post-enumeration survey estimates, the demographic analysis estimates, and the small area synthetic estimates.

Discussion

The general rationale for this decision is clearly stated in the first section of this report. The technical documentation underlying this decision is in keeping with the professional standards of the statistical community. Thus the Guideline has been satisfied.

However, the Guideline could have been met if the decision had been to adjust. The Census Bureau has done a laudable job of keeping the public informed of the progress of the post-enumeration survey and the progress towards the adjustment decision. There is no doubt that the process of adjustment is complex and the statistical details of the process are fully comprehended by only a few individuals. Although I am sympathetic with these arguments, this would not have been an impediment to an adjustment. The general rationale could

[137] Tarrance, pages 2–3.

[138] Estrada, page 24.

[139] Estrada, page 23.

[140] See appendix 15. Murray, Michael, "Census Adjustment and the Distribution of Federal Spending," U.S. Bureau of the Census, May, 1991, [hereafter Murray].

have been clearly articulated. As Estrada notes, the public perception of the census "head count" is far removed from the actual process, [141] yet the general rationale for the census is well understood.

Conclusion

The requirements for this Guideline have been met. This Guideline does not weigh in favor of a decision either way since the requirements of this Guideline could have been fully met if the decision had been to adjust.

SECTION 3—SUMMARIES AND EVALUATIONS OF THE RECOMMENDATIONS OF THE SPECIAL ADVISORY PANEL

In this section I summarize the individual recommendations of each of the members of the Special Advisory Panel appointed to advise me on this decision, and the joint recommendation offered by Drs. Ericksen, Estrada, Tukey, and Wolter. After each summary I evaluate each recommendation.

Recommendation of Eugene P. Ericksen

Summary of the Recommendation

Ericksen recommends an adjustment. His argument relies substantially on a report co-authored by himself, Estrada, Tukey, and Wolter. He argues as follows: An adjustment will reduce the substantial error in the census and will correct for the differential undercount. The Bureau produced a demonstrably inaccurate census enumeration which can be fixed by means of PES estimates. PES estimates have been demonstrated to be both accurate and statistically reliable by evaluation studies of the 1990 decennial census. The racial differential undercount has again been demonstrated in the census, and the PES can correct for this clear and important bias.[1]

On Guideline One, Ericksen reports from his jointly authored analysis and other analyses that it is clear the adjusted count has been shown to be more accurate than the original enumeration. In Ericksen's view there is little doubt that the original enumeration is inaccurate. He states that the Census Bureau reported 13 million erroneous enumerations, 19 million omissions, and a PES net undercount rate of 2.1%.[2]

Ericksen says the basic flaw of the original enumeration is that it uses a method "designed for the well educated, middle-class family with reliable mail service." He argues that the method does not work for "those who do not read well, who live doubled up in an apartment, who live in drug infested neighborhoods with high crime rates, and who only occasionally receive mail." The procedure had such well demonstrated flaws that the 4.7 million undercount, and the 4.4% demographically estimated differential, was not surprising.[3]

Ericksen states that the PES was successful. The interviewing quality was high, imputation was minimal, and the matching error was very small. The evaluation studies suggest that the total error in the PES was minor. Correlation bias suggested that the PES underestimated the undercount, if anything. "The only reasonable conclusion is that the adjusted count is more accurate than the unadjusted count." [4]

On Guideline Two, Ericksen states that the adjusted data are consistent, complete, and of sufficient quality to be used for all purposes and at all levels for which census data are used. He cites the jointly authored report.[5]

On Guideline Three, Ericksen finds that "under any reasonable basis of comparison, the PES-adjusted enumeration is more accurate than the unadjusted enumeration." [6] The PES estimates are robust with respect to evaluation strata, and the effect of the PES biases on population shares is negligible. The estimates for the states whose Congressional delegation size might be changed by an adjustment are stable.

On Guideline Four, Ericksen says it is difficult to comment because of the lack of evidence. He interprets the available evidence from a National Opinion Research Center (NORC) study to suggest that most Americans would like to have the most accurate census and will trust the experts to make it so.[7]

Ericksen has no expert opinion on Guideline Five but notes that Jefferson lamented the lack of accuracy in the first census.

On Guideline Six, Ericksen feels sufficient data are available to make the decision now. Sampling errors for local estimates are reasonably small, and the PES evaluation studies indicate that bias is small.

On Guideline Seven, Ericksen admits having little comment. As a scientist he feels it is better to use improved numbers when available than to rush ahead and make errors.

On Guideline Eight, Ericksen believes that the results can be explained, and the technical documentation is in keeping with professional standards.

Evaluation of Recommendation

I agree the census had an undercount. I also agree that the evaluation studies demonstrated that the PES was well done. I do not agree, however, that the PES has the ability to correct distributional error. The grounds for my disagreement have been documented in the discussion of Guideline One.

I agree that the adjusted count, if more accurate, has been shown to be more accurate in a numeric sense at the national level. I do not agree that the adjusted count is more accurate in the distributional sense at lower levels of disaggregation. In addition, the erroneous enumeration and omission figures cited are Census Bureau estimates, which vary according to definition.[8]

The census used a variety of methods, including mail-out/mail-back, list enumerate, and list leave to fit different lifestyles. Class membership, education level, and reliability of mail service may explain some, but not all, of the census coverage problems. Recall that the personal enumeration censuses of 1940, 1950, and 1960 had even higher estimated undercounts. Thus, I disagree with Ericksen's notion that the census was "designed for the well educated, middle-class family with reliable mail service."

I do not agree that successful PES operations imply that the statistical manipulation required to go from its data to 4,830,514 blocks in order to produce a better count is a routine, automatic operation. I disagree that PES data, which are informative about the census, *can* be used to change the census in ways that make it distributionally more accurate.

I do not agree that merely because the Census Bureau can produce data that completely duplicate enumeration tables, that those numbers are of sufficient quality to be substituted for the census enumeration.

[141] Estrada, page 24.

[1] Ericksen, p. 1.

[2] Ericksen, p. 2.

[3] Ericksen, p. 2.

[4] Ericksen, p. 3.

[5] Ericksen, p. 3.

[6] Ericksen, p. 3.

[7] Ericksen, p. 3.

[8] The numbers used by Ericksen are estimates derived from all P-sample misses (19,171,290) and all E-sample "Erroneous Inclusions/Unmatchable." (13,154,639) While defensible, this is but one extreme definition. For example, it does not take into account the role of Census imputations. The matter of estimating these two components is a matter of disagreement among professionals. See, for example, the discussion in a Memorandum from Howard Hogan to Pete(r) Bounpane entitled "Gross Census Errors," July 2, 1991, Bureau of the Census on these issues. See the discussion of this issue under Guideline One above.

I agree that the PES adjusted enumeration may be more accurate numerically. I do not agree that it is distributionally more accurate. While the estimates are robust for evaluation strata, there is considerable doubt cast on their homogeneity with respect to post-strata relative to states.[9]

I appreciate Ericksen's comments on Guidelines Four and Seven, although I do not agree with them. I agree with his comments on Guideline Eight. I agree with his comments on Guideline Six, except that sufficiency of data in Guideline Six has nothing to do with substantive outcome, as Ericksen's comments about the size of sampling error would seem to imply.

Recommendation of Leobardo F. Estrada

Summary of the Recommendation

Estrada recommends in favor of an adjustment. Estrada first spells out a general rationale for his decision which is followed by an exposition of his reasoning for each guideline. Estrada relies on the paper co-authored by Ericksen, Estrada, Tukey, and Wolter.

Estrada's general rationale begins with the observation that the 1990 census is sufficiently flawed to require adjustment. In particular, the undercount rate increased from 1980, the census omitted the largest number of persons ever, historical undercount differentials between blacks and non-blacks persisted, and the black non-black differential actually increased from 1980 to 1990.[10]

Estrada states that the observed pattern of undercount is consistent with prior censuses. The Census Bureau efforts to overcome the undercount in the enumeration failed for a variety of reasons relating both to the character of the population and to the nature of the census operation itself. "While the Census Bureau was able to improve its internal management systems, the national dynamics that comprise the U.S. became more complex." [11]

Estrada argues that the differential undercount was the real cause for concern. He asserts that it occurred due to a number of problems in census processes. Flaws in the census operation included inaccurate mailing lists, non-delivery of census forms, a lower than expected mail return rate, inadequate interviewer and enumerator staffing levels, delay in district office closings, enumerator errors, enumeration by last resort, missing data, the inclusion of 2 million non-data defined persons in the count, lack of non-English language forms, processing errors, lost forms, race and ethnicity misclassifications, geocoding errors, and duplicate records.[12] District offices in the largest cities with the most heterogeneous populations suffered more from these flaws than others resulting in more last resort, close-out and non-data defined enumerations among non-Hispanic blacks and Hispanics.

Estrada states that the cumulative effect of all these problems is that the 1990 census needs adjustment.

Estrada describes the post-enumeration survey (PES) as a high quality process. He ascribes the high quality of the PES to, among other things, on-site listing of livable structures rather than reliance on mailing lists in sample blocks, experienced interviewers, a non-response rate of less than 1% and a proxy response rate of only 2.4%, relatively early interviewing to overcome the forgetting problem, successful tracking of the 8% of the PES who were movers, the successful evaluation program, and the fact of matching or resolving non-match cases for 98.3% of the 173,000 housing units surveyed.[13]

Estrada says that PES estimates of undercount follow known and expected patterns; *i.e.*, blacks higher than non-blacks, young males among minorities most often undercounted, the West division higher than other divisions, Hispanics highest rates of all. This attests to the "reasonableness" of PES undercount estimates and shows consistency with demographic analysis.[14]

Estrada claims the quality of the dual system estimates is sufficiently high to justify their use, according to the Hoaglin and Glickman sensitivity analysis among others.

Estrada says that adjustment methodologies improve the proportional distribution at all levels of census geography. He relies on the Tukey work and the work of other consultants that show that improvement at higher levels of geography improves shares at lower levels.

These conclusions by Estrada end the general rationale section of his recommendation The remainder of Estrada's recommendation focuses on each guideline.

On Guideline One, Estrada begins by reviewing the results of the Census Bureau evaluations of the PES, the so-called P-studies. The missing data studies (P1, P2 and P3) show that the rates of noninterview are low and the imputation for the primary population items was also low. Alternative means of imputing missing data did not affect post-strata. A Special Advisory Panel (SAP) analysis shows that post-stratum shares are minimally affected by eight alternative ways of handling missing data, with one exception. Given the small number of imputations required for the PES, alternative methods would have small effects on the outcomes.

Estrada says that the matching error studies (P7 and P8) confirmed that the high quality of clerical matching and matching of movers was performed successfully.

Estrada writes that the correlation bias studies (P13, P14, and P17) show strong correlation bias in the PES. Although for some this casts doubt on the dual system estimates, for him there is another side to the coin—"the undercount would be underestimated, particularly for minority populations. Whether the underestimation of undercount caused by correlation bias balances the biases toward overestimation of the undercount caused by missing data needs to be investigated, but the chances are they offset each other." [15]

Estrada states that other studies of data quality from the PES (P4, P5, P5A, and P6) show that the PES was not seriously impaired by problems of the quality in the reported census day addresses or fabrication.

Estrada says that those studies related to erroneous enumerations (P9, P9A, P10) show that erroneous enumerations were concentrated in particular evaluation post-strata. The census had higher rates of erroneous enumerations in minority areas and rural areas. Some significant changes would have occurred had matching of cases reported as erroneous enumerations been done by expert matching. On the census side there was a low error rate in matching, but more detailed analysis indicates that erroneous enumerations due to matching were more likely in two evaluation post-strata—non-minority areas outside the central city in the Northeast and West.[16]

Estrada claims that the study on late-late census enumerations (P18) shows that the addition of these data had an insignificant effect on the undercount rate. Similarly, balancing error was not a problem.

[9] See P12, and the discussion of Guideline Three above.

[10] Estrada, page 2.

[11] Estrada, page 3.

[12] Estrada, pages 4–6.

[13] Estrada, pages 6–8.

[14] Estrada, pages 8–9.

[15] Estrada, page 14.

[16] Estrada, page 16.

Estrada believes that the total error model (P16) indicates that errors introduced in the PES were small and tended to equalize racial differentials in the undercount.

On Guideline Two, Estrada states that a strong argument can be made that the requirement for local area accuracy can be satisfied by showing that adjusted counts are an improvement on the average for the principal uses of census counts. He claims it is appropriate to judge the adjusted counts at higher levels of aggregation than the block.

Estrada acknowledges that the Census Bureau study on heterogeneity (P12) shows mixed results with respect to the homogeneity assumption with respect to poststrata. "The research 'flags' the need to be aware of State effects [overwhelming poststrata effects]." [17]

On Guideline Three, Estrada acknowledges that the Census Bureau study on coefficients of variation (P15) showed that estimates of variances and covariances for smoothed and unsmoothed adjustment factors were larger than expected. However, he cites the Hoaglin and Glickman study as demonstrating the robustness and stability of the dual system estimators under different statistical treatments.

On Guideline Four, Estrada argues that if the Secretary adjusts using the best tools available, the reputation of the Census Bureau will be enhanced. The census process must incorporate adjustment as its final step. Estrada interprets the National Opinion Research Center (NORC) poll as indicating that the decision to adjust is slightly more likely to improve participation in future Censuses.

On Guideline Five, Estrada states that the innovation of adjustment is in keeping with prior Census Bureau efforts to meet the intent and spirit of the Constitution. The courts have already held that adjustment can be Constitutional.

On Guideline Six, Estrada states that "all the proposed studies have been completed, the data tables made available and the Census Bureau has had sufficient time to fulfill the concerns set out by [this guideline] in time for the Secretary of Commerce to make his decision." [18]

On Guideline Seven, Estrada states "Without denying the fact that there are State officials who feel imposed upon and elected officials (and potential challengers) who suffer from uncertainty as to when the boundaries of their districts will be 'fixed,' the actual consequences [of the census being adjusted and these figures not being available until July 15, 1991] are that a couple of Congressional seats will shift from one State to another; that delays will occur in redistricting, and that edges of many recently designed districts will have to be slightly modified to meet the one-person, one-vote requirements." [19]

Estrada says these disruptive consequences must be weighed against the fact that a census adjusted for deficiencies will provide a more equitable allocation of persons to each district, and a more equitable allocation for all other census purposes. The public good is better served by focusing on the potential benefits of adjusting the census to millions of persons rather than on the limited number of Congressmen and Congresswomen and legislative officials who will be affected by the July 15, 1991, decision to adjust the census and the subsequent release of adjusted numbers.[20]

On Guideline Eight, Estrada states there is an implicit assumption that the public understands the standard census methodology. However, their perception of what the census is—is far from the real census. Thus, both the real census and the reason for adjusting the census must be understood by the public. The public must understand the context of the PES in the census process. An informed public will accept the need to adjust if provided with concepts to understand the logic of the method.[21]

In conclusion, Estrada notes that the census has suffered from a persistent differential undercount. The evidence overwhelmingly demonstrates that the census count can be improved by adjustment. The PES adjustment factors have an advantage over demographic analysis in providing more specificity about the undercount. Adjusted counts will be more equitable and assure equal representation. Therefore, the Secretary of Commerce should adjust the census.

Evaluation of Recommendation

I do not agree that it follows that even were the 1990 census sufficiently flawed to require an adjustment, an adjustment is possible. The facts cited comparing 1980 and 1990 are a necessary, but not sufficient, grounds for considering an adjustment. A methodology must be available that will achieve a successful distributional correction.

I agree that the differential undercount is regrettable, and a cause for serious concern. I do not agree with Estrada that the flaws cited in the census are tied directly to that undercount. I agree that no matter how the differential came about, one would want to fix it *if one could.*

I agree that the PES was successful. However, I do not agree that the PES estimates followed all expected patterns. For example, in the discussion of Guideline One, above, serious questions are raised about its success in finding black males, and its "over compensation" for older females. In fact, PES results are frequently inconsistent with demographic analysis.[22]

I believe that the Hoaglin and Glickman study can be interpreted to show not robustness, as Estrada says, but that it can be interpreted to show that thirteen different models produce thirteen different sets of adjusted counts. These counts may have been close to one another, but not necessarily be an improvement over the census. Furthermore, as I noted in the discussion of Guideline Two there are other sources of variation due to statistical modeling.

I do not agree that the conclusions reached with respect to the Panel correlation bias studies are as clear as Estrada asserts. As Special Advisory Panel member Wachter suggests, the undercount may be underestimated by correlation bias effects not because of differential misses, but by differential erroneous enumeration rates when holding misses constant.[23]

I believe that Estrada's discussion of erroneous enumerations reaches the opposite conclusion from what the studies find: Differential erroneous enumeration rates by evaluation post-strata are a cause of concern, because they leave open the real possibility of differences between processing offices in how well the PES was carried out.

I agree that the total error model is experimental, but I disagree that the expression "total" is appropriate. Not all errors are included in it, only those errors that could be estimated on the basis of the PES. While the study of total error is encouraging, it is not yet dispositive with respect to the utility of the model.

Estrada acknowledges that P12 shows mixed results with respect to heterogeneity of post-strata. Thus, his assertion that requirements for local area accuracy are satisfied by "average improvement," and that only higher than block levels of aggregation need be considered, seems to me to contradict his acknowledging that local area

[17] Estrada, page 19.
[18] Estrada, page 23.
[19] Estrada, page 23.
[20] Estrada, page 23–24.
[21] Estrada, pages 24–25.
[22] See the discussion of Guideline One above.
[23] Wachter, pages 12–13.

accuracy needs to be satisfied. In fact, heterogeneity at the block level would mean that Guideline Two has not been satisfied.

As noted earlier, I believe that the Hoaglin and Glickman study can be interpreted as demonstrating a clear lack of robustness: Since accuracy at the block level is the goal, a process that allows thirteen different models to produce thirteen different estimates that differ only a little from one another, is not adequate. Differing a little at the high level of aggregation of the Hoaglin and Glickman work may mean differing dramatically at the block level.

I do not agree with Estrada's comments on Guideline Seven. The adjustment, as envisioned, will, in fact, not provide a more equitable allocation of persons to districts as he assumes. In my opinion, the lack of distributional accuracy is precisely why the adjustment is flawed as a correction for the census counts.

I do not agree that adjusted counts will be more equitable as Estrada claims in his discussion of Guideline Eight. In fact, they will not be more equitable distributionally, which is the criterion for determining whether an adjustment would improve the accuracy of the counts.

Recommendation of William Kruskal

Summary of Recommendation

Kruskal recommends against an adjustment. He uses the word "modification" rather than adjustment since the latter term suggests to him that "we really know how to improve the Census enumeration." [24] The primary reason for recommending against adjustment is that "we do not know with any confidence how to make such improvements . . . and we will not know in a relevant time scale." [25] Although "the proposed modifications are clever and technically interesting, the method turns on highly specialized assumptions and we simply do not know how robust the output results are against realistic errors in those assumptions." [26] The proposed modifications are complex, impossible to explain clearly for a general audience and their use is "likely to increase already existing apprehensions about manipulation and big brotherism in Washington." [27] The modified estimates might well introduce more error than they clear up, without anyone being aware of such an imbalance.

On Guideline One, Kruskal contends that there is no conclusive evidence that the modification removes more error than it introduces, and does not expect any convincing arguments anytime soon. The major gap in assessing comparative accuracy is the uncertainty about the "capture-recapture" model.[28] The implicit assumption of uniform capture probability is the most troublesome. Knowledge about the degree of output error caused by the non-factuality of this assumption "is just what we do not have, indeed cannot have, for the post-enumeration process." [29]

Later Kruskal notes that Guideline One calls for the highest professional judgment from the Census Bureau. "The highest level of professional judgment requires vigorous argument and discussion not only within the Bureau but in groups made up both of Bureau and outside statisticians and others. That vigorous and public discussion we have not had in nearly adequate amount." [30]

On Guideline Two, Kruskal's only comment is that synthetic adjustment is based on a simplifying assumption that is known to be wrong, which in turn throws great weight on the calculations of stability, given reasonable error structures.[31]

On Guideline Three, Kruskal's impression is that "choice of the so-called smoothing procedures was profoundly based on post-enumeration survey (PES) results," [32] which is not in keeping with the guideline. He questions whether "that in *major* respects the choice of procedure was made before the PES results were in hand," but time did not permit a full investigation on his part.

On Guideline Four, Kruskal feels the extraordinarily complicated procedures will undercut public confidence in the census. On Guideline Five, Kruskal has no comment. On Guideline Six, Kruskal believes that "timely data and analysis are not really at hand." [33] On Guideline Seven, Kruskal does not see how "this cuts in the present context." [34] On Guideline Eight, public explanation will be difficult because of the complexity and the choice of one of many such methods available.

Kruskal notes that the Guidelines "tilt against modification," but "that is hardly novel." [35]

Without resting his views solely on the guidelines, and instead on his "partly formulated and internalized professional criteria, along with [his] internalized civic standards," [36] Kruskal still recommends against an adjustment. He expresses concern about the large numbers of estimated counts and the inherent problem of putting together the millions of estimated differences between the count and the adjustment. He closes by noting that modifications that increase counts can, in fact, harm, by moving the proportions of the population in a given area in the wrong direction.

Evaluation of Recommendation

I agree that the census modifications lack robustness. Thus, Kruskal does not interpret the Hoaglin and Glickman studies as do plaintiffs' panel members. He recognizes that the adjustment may introduce more error than they correct without anyone knowing it.

I agree with Kruskal's criticism of the "capture-recapture" model upon which the DSE is based. He notes, in particular, that its assumption of uniform capture probability is most troublesome.

I agree with Kruskal's belief that there has not been an adequate vigorous and public discussion of the merits of adjustment. However, I disagree with his statement that the lack of such a discussion means we are not able to determine whether Guideline One is adequately met.

I disagree with Kruskal that, in terms of Guideline Three, there was no prespecification. He asserts that smoothing procedures were based on PES results. His comments implies a standard that would, in Guideline Three terms, preclude ever meeting prespecification requirements.

I agree with his comment that increasing counts can move proportions of the population in a given area in the wrong direction. That comment means that he, too, is concerned with the problem of distributive accuracy, and that he shares a concern about whether the proposed procedures deal with it adequately.

Recommendation of Michael McGehee

Summary of Recommendation

McGehee strongly recommend[s] that no adjustment be made to the census. There is no compelling evidence that suggests that the

[24] Kruskal, page 1.
[25] Kruskal, page 1.
[26] Kruskal, page 1.
[27] Kruskal, page 1.
[28] Kruskal, page 2.
[29] Kruskal, page 3.
[30] Kruskal, page 5.
[31] Kruskal, page 3.
[32] Kruskal, page 4.
[33] Kruskal, page 5.
[34] Kruskal, page 5.
[35] Kruskal, page 5.
[36] Kruskal, page 6.

PES [post-enumeration survey] will provide estimates that are any closer to the true population totals for the eight million blocks in the United States. Indeed, there is significant evidence to suggest that adjustment will move the population of many blocks further away from their true populations.[37]

Persons have always been missed in the census for a variety of reasons. Statistical adjustment is the most recent proposal to address the situation. [38]

McGehee states that adjustment numbers are estimates just like census counts: there is no way to determine which is closer to the true population, other than assumption and judgment. The evaluations of PES data "rested on pre-conceived assumptions of how the data would appear." [39] The results often fell outside the limits predicted from these assumptions. Rather than accepting the conclusion that the process is flawed, the assumptions were modified. He has no confidence in this reasoning. He refers to the problem in computing margins of error (variances) for local estimates as an example of this problem. "It is a strong indictment of the entire process, however, when evaluation procedures are not clearly understood by those using them * * *. The entire process has tended to produce more, rather than less, uncertainty." [40]

McGehee gives, as an example of the uncertainty created, the large difference in production matching effectiveness rates between Albany and Kansas City (87.20% v. 93.49%). Why this discrepancy exists is unknown and "no documented evidence can be presented which clearly explains this problem." [41] Adjustment proponents will argue that in the aggregate these problems are small and thus "the differences at lower levels should be overlooked because they become insignificant at the aggregate level." [42] McGehee disagrees, pointing to Guideline Two requiring accuracy across all jurisdictional levels. Furthermore, variation at the aggregate level, McGehee contends, is discounted by proponents by modifying the assumptions upon which the conclusions have been based.

"Decisions made during the DSE process, and the assumptions on which they stand, dramatically alter the adjustment results. A politically 'better' count cannot be defended if it is shown that the assumptions on which it rests are changeable." [43] Because of the widespread use of census figures, they must be defensible. The Bureau has maintained public confidence in its numbers over the years by "its meticulous approach to detail and its dogged adherence to maintaining the quality of Bureau data as the true standard." [44] Adjustment will undermine the public's confidence in this track record. A decision to adjust should be treated as political, and be forced to undergo the same Congressional scrutiny as other such decisions.

McGehee continues his argument by discussing the capture-recapture methodology. He uses an analogy to compare the PES to counting bears in a game preserve. He notes that the heterogeneity in game wardens' background and abilities, in the types of bears and their physical characteristics and in the terrain will lead to differences in how well the bears are counted. In similar ways, the enumerators' characteristics, the characteristics of the population the enumerator is counting and the environment in which the enumerator is working will all have effects on the outcome of the PES. These problems are compounded by the fact that PES records must be matched back to the census and the ability of matchers may be heterogeneous. [45] To identify the weight given to each of these variables, regression models are used to determine their individual effect. How these regression models are specified in the PES process is constantly changing. How to combine these variables into a larger number and how to compare various strata are issues of judgment on which individuals may differ. [46]

McGehee says that comparisons of data to the "correct" or "true" population are often made. The "correct" population is derived from a series of assumptions and thus results are simply theories. After reviewing the data, it is clear that the proposed adjustment does not meet the criterion of being usable across all jurisdictional levels nor is it robust at local levels to reasonable alternatives. The idea of using the PES to adjust the census is so complicated and so subjective, that no reasonable person can agree that it should be contemplated or that the process will be explicable to the general public. [47]

McGehee next turns to the issue of comparing the accuracy of the PES to the Census. Matching PES and census records is the key to assessing the relative success of the PES and the census in counting people. His "analysis shows that the PES fails to demonstrate a 'better' record of counting people than the Census. Indeed in many instances it cannot demonstrate that it did *as well* as the Census." [48] In support of his assertion McGehee presents a cross tabulation of census match codes by race and ethnic origin. He also does so for the PES. Although "time does not permit extensive analysis of this data," [49] he does note that twice as many Hispanics in the census left the race question blank as in the PES. More Hispanics identified themselves in the category "other" in the PES than in the census. "On a superficial basis, the results raise very significant questions whether adjustment will, in fact, yield greater accuracy than the census." [50]

McGehee states that the rationale for using the PES to correct the differential undercount rests on the assumption that as the black population increases in each block cluster, the PES will do a better job than the census in counting people. [51] It is appropriate then to compare the "best" and "worst" census and PES numbers within each block cluster and see how these comparisons change as the concentration of blacks increase over clusters.

McGehee argues that since errors occur in both the census enumeration and the PES survey, judgments had to be made as to whether it was correct to include them. These judgments are critical in determining the success or failure of the PES or the census. In those cases where judgments were made, one can get a range of estimates of quality by assuming that all judgments should have gone in favor of omission and, alternatively, all judgments should have gone in favor of inclusion.[52] Best and worst confidence level scenarios for the census and the PES in each block cluster are carried out. These comparisons are displayed by ranking the results in order of the proportion of blacks in the cluster, since research indicates "that as the percentage of black population within a cluster increases, the effectiveness of census coverage decreases." [53]

[37] McGehee, page 6, emphasis in the original.
[38] McGehee, page 2.
[39] McGehee, page 3.
[40] McGehee, page 4.
[41] McGehee, page 4.
[42] McGehee, page 5.
[43] McGehee, page 5.
[44] McGehee, page 6.
[45] McGehee, pages 8–10.
[46] McGehee, page 11.
[47] McGehee, page 12.
[48] McGehee, page 14.
[49] McGehee, page 19.
[50] McGehee, page 19.
[51] McGehee, page 20.
[52] McGehee, page 21.
[53] McGehee, page 26.

McGehee uses six graphs to present these results. "When comparing the best census scenario with the worst PES scenario one sees that the census does a dramatically better job of correctly counting people than the PES. . . . What is surprising, however, is the potentially dramatic performance shown by the census in those clusters where the black population is between 50% and 75%. Even more surprising is the very close correlation between the census and the PES in clusters where the black population is greater than 80%. In fact, the Census has a higher confidence level than the PES in those clusters where the black population is between 80% and 85%. This flies in the face—and graphically demonstrates the fallacy—of the argument put forward by the proponents of adjustment." [54] The PES does not necessarily outperform the census. Even if one accepts the midpoint between the best and worst PES results, the census exceeds this level and the PES does not outperform the census in clusters containing a large number of blacks.[55]

McGehee then turns to the guidelines. In his discussion of Guideline One, he finds the entire concept of adjustment on "the outer limits of statistical research." [56] The assumptions underlying the evaluations of the PES are so arbitrary and fluid that little weight can be attached to their assessments of PES quality. Therefore, Guideline One cannot be met since one cannot prove that the PES is better than the census.

On Guideline Two, he notes that variances between processing offices and evaluation strata are outside expected levels and at the district office level there was such variation it could not be reconciled. Adjusted numbers are inconsistent at the State, city, and subcounty level and suffer from serious quality concerns.[57]

On Guideline Three, McGehee asserts that the adjusted counts have not been shown to be more accurate than the census enumeration. The determination of quality is dependent on many assumptions and judgments.

McGehee says that the manipulation of assumptions in evaluation studies undermines confidence in all ongoing statistical data collection and therefore Guideline Four cannot be met.[58]

McGehee claims there remain legality questions about adjustment that need to be answered with respect to Guideline Five. On Guideline Six, McGehee states that sufficient data are available to suggest that the PES was flawed and the analysis of the data is insufficient to justify a decision to adjust the census.[59]

On Guideline Seven, McGehee finds that the mere fact of a possible adjustment has caused consternation and difficulties in state legislatures. The lack of consensus on the desirability and statistical feasibility of adjustment will result in extensive legal battles.[60]

Finally on Guideline Eight, McGehee asserts that the entire process is so complicated and difficult to understand, even by professionals, that a general rationale cannot be clearly justified. To the degree that the process is explained successfully people will become aware of the kind of manipulations underlying it and the integrity of the statistical process will be forever compromised. Adjustment is to correct an inequity, which is not a statistical problem but a political and societal problem that should be dealt with by the Congress.[61]

Evaluation of Recommendation

I agree with McGehee that the results of the PES fell outside expectations. The error variance around local estimates are an example of this problem.

I agree with McGehee's citing large differences in production matching effectiveness between processing offices as indicators of uncertainty rampant in the PES data. However, evaluation studies of the PES have not found the kind of systematic effect alleged.

I disagree that the link between the Bureau's credibility and its aversion to schemes that tend to devalue the census itself is a reason for avoiding adjustment.

I agree with McGehee's criticisms of the capture-recapture methodology. He raise issues not brought out elsewhere that cast doubt on its validity for use on human problems. I agree with his notion that characteristics of interviewer, interviewee, and setting interact to affect the quality of information, and find McGehee to persuasively elaborate the idea. I believe that McGehee's ideas support criticisms of Kruskal and others that the method is flawed fundamentally.

I disagree that if an adjustment were made it would not be explainable to the public. Since the decision not to adjust is just as complicated, this statement does not seem to have merit as an argument against adjustment.

Although I concluded that an adjustment would degrade the quality of the population distribution as compared to the census, I do not agree with McGehee's explanation of why the PES did not do as well as the census. He presents an analysis showing that, in a sample of block clusters, as the percentage of blacks within a cluster increases, the census actually performs better than expected. McGehee claims that this analysis casts serious doubt on the argument that *ipso facto* a PES based adjustment will necessarily reduce the differential undercount of blacks. I find his argument at best anecdotal and not compelling.

I agree with McGehee's conclusions that, on the basis of his analyses, arguments for adjustment based on Guidelines One, Two, Three, and Six are not adequate: The census remains more accurate than the PES; adjusted numbers are inconsistent at different levels of geography, and the quality of the PES is too dependent on assumptions, not facts and analysis.

McGehee argues on Guideline Seven that disruption is already occurring. This argument lacks support. He cites no evidence that adjusting or not adjusting will differentially contribute to disruption. Thus, I find that his arguments that this Guideline argues against adjusting are not relevant.

I disagree with his belief that the technicalities cannot be explained. Rather, I note that the process has been open, the Bureau has gone to great lengths to document its activities, so that there was no lack of ability to explain adjustment.

Recommendation of V. Lance Tarrance, Jr.

Summary of Recommendation

Tarrance recommends against an adjustment. He has chosen to concentrate on the public policy implications of a decision, not only because it is his area of expertise but also because he is "convinced that the impact of changes to the enumeration totals on the operations of our government—at the federal, state and local levels—would be disastrous." [62] Tarrance's lengthy introductory remarks are followed by a discussion of the guidelines.

Tarrance states that the perception that if the Bureau discovers how many persons it missed it should be an easy task to correct census results is

[54] McGehee, page 28.
[55] McGehee, page 29.
[56] McGehee, page 31.
[57] McGehee, page 32.
[58] McGehee, page 33.
[59] McGehee, page 33.
[60] McGehee, page 34.
[61] McGehee, page 35.
[62] Tarrance, page 1.

incorrect. In fact, there is no consensus on how to fix the counts among statisticians or other experts. Two Gallup polls—March 1990 and April 1991—show no consensus on including estimates of missed persons in the count. Whites were evenly split; non-whites preferred a synthetic adjustment.[63]

Tarrance says that more important than the statistical quality of the numbers is the public policy aspects of an adjustment. These include "the paralyzing difficulties that changing the numbers will cause in accomplishing redistricting . . . for all levels of the electoral system; the damaging perceptions that will be given to the public about the two different sets of numbers from the census; the troubling uncertainties surrounding even statistically acceptable numbers . . ." [64] Such policy difficulties should not be dismissed as many proponents of adjustment have done.

Tarrance asserts that lost in the debate fostered by adjustment advocates are the following points of decisive importance: (1) The adjustment process is complex, not well understood, without precedent and evaluations of it are judgmental; (2) synthetic estimates below the State level will never be more accurate than census counts; (3) the deadline of July 15, 1991, has not allowed enough time for adequate evaluation of the adjustment process or its product; (4) two sets of numbers may create "chaos" for the 1992 elections; (5) the trust in census confidentiality and the belief in the need to cooperate with the census will be further eroded; (6) resources may be denied to future census activities because "adjustment will take care of all problems" will be the expedient prevailing attitude; and (7) accepting adjustment will invite " 'inside manipulation' of numbers for political purposes." [65]

Tarrance says that "The adjustment process being used can produce an array of different results depending on the choice of assumptions and/or statistical methods employed. . . ." [66] Thus, the issue is not technical, but judgmental, as the decision calls for an assessment of the consequences of a decision. Whatever the decision, litigation will ensue, but a decision against adjustment "may be the beginning of a more reasoned look at the problem." [67] The Constitution says Congress shall determine how the census is to be conducted; therefore Congress should settle this issue, if at all possible, rather than the courts.

Tarrance quotes a statement made by co-chair Ericksen in 1980: "The undercount adjustment procedure needs to be statistically sound and politically credible," and goes on to state that the controversy has increased, in fact, and Ericksen's 1980 position is even more compelling today. Given the confusion and possibly paralyzing effects of adjustment, the best solution is not to adjust the census today, but to consider the proposal to adjust intercensal estimates as is done in Australia, Finland, and Spain.

On Guideline One, Tarrance first notes that statistical sampling only produces accurate results when sample sizes are sufficiently large, and for small jurisdictions this is simply not the case. Some small area counts will be made less accurate by an adjustment and the question is how we deal with such areas. There are a host of questions about tradeoffs among communities in accuracy that remain unanswered.

Furthermore, he points out that accuracy is a point of fundamental definitional differences between law and statistics: law needs certainty, statistics accepts a range of uncertainty about numbers it still considers accurate. "Any court settlement directing adjustment will *necessarily* require the arbitrary choice of numbers which have been derived from methods that statisticians would ordinarily hedge about. . . . It is paradoxical that those same interests who are faulting the Bureau of the Census for not having counted all persons are at the same time putting inordinate trust in that same agency to transcend the limits of statistical 'estimating!' " [68]

Tarrance argues that:

> The important fact that is buried in the mass of rhetoric about the need to correct inequities resulting from undercounting is that the numbers will undoubtedly be less accurate for many areas below the state level. The reality is that the adjustment process will not find those persons who were missed by the original enumeration and include them where they were not counted before. . . . Some correctly counted blocks could have persons added to their count; some correctly counted blocks could have persons deleted from the census count, and incorrectly counted blocks might not have any changes made to their numbers.[69] In addition, the post-enumeration survey (PES) is not able to handle all forms of counting errors with equal adequacy. Thus, misallocation can still occur even with adjusted numbers. Ultimately, "the final numbers are chosen from a range of possibilities that are dependent upon the choice of assumptions; there is a great deal of 'inside' judgment involved, and although [he has] no reason to doubt the experts at the Bureau of the Census who have had to make the hard choices, it is still troublesome that there is an opportunity for different results to be obtained by the use of different methods or assumptions." [70]

On Guideline Two, Tarrance states that a lack of usability for redistricting is a major deterrent to proceeding with adjustment, because of the conflicts having two sets of numbers will generate. "The realities of redistricting at the state and local level, combined with the possibilities for endless litigation, are such that it would be naive to believe that synthetic numbers will be usable . . . for the purposes of redistricting and reapportionment." [71] With two sets of numbers, redistricting plans will likely end up in court and the likelihood of "chaos" for the 1992 elections seems ever more probable.

On Guideline Three, Tarrance is most troubled by "the acknowledged fact that different methods using different assumptions produce different results." [72] As an example he notes that small numerical differences lead to large consequences in reapportionment and redistricting. "It is all too obvious that the procedures being used will not produce robust numbers and that it would be possible to obtain an array of population counts which could have very different effects upon apportionment." [73]

The requirement for pre-specification in Guideline Three concerns Tarrance, as some procedures were prespecified and some were not. In particular the decision not to combine demographic analysis with the PES was made by staff, in stream. This is an example of an attitude of "if the numbers don't come out the way we think they should, we can change plans" which is "diametrically opposed to what good government policy should allow. Furthermore it is clear that the adjustment process is a statistical operation which has never been done before and there are many last-minute decisions being made." [74] Tarrance

[63] Tarrance, page 2 and Appendices.
[64] Tarrance, pages 2–3.
[65] Tarrance, pages 4–5.
[66] Tarrance, page 6.
[67] Tarrance, page 7.
[68] Tarrance, page 13.
[69] Tarrance, page 13, emphasis in the original.
[70] Tarrance, page 16, emphasis in the original.
[71] Tarrance, page 18.
[72] Tarrance, page 19.
[73] Tarrance, page 19.
[74] Tarrance, page 21.

expressed uneasiness that "special interest pressure to adjust was pushing an incompletely researched or insufficiently tested statistical operation to a very shaky end".[75]

On Guideline Four, Tarrance states that a decision to adjust would have a far-reaching impact on future census efforts. Future censuses might be adversely affected as the Congress might well cut census funds, using the logic that an adjustment will fix the count anyway. Mayors and other local officials would question the necessity for their efforts on behalf of the census. The adjustment controversy might very well erode the already tenuous confidence of the public in the Census Bureau. The controversy surrounding the count should lead to imaginative ways to take the census in 2000, such as rolling samples, the "bare bones" head count, *etc.;* and legislative proposals immediately after the adjustment decision.

On Guideline Five, Tarrance states that Congress should determine how the census is to be conducted as required by the Constitution. Congress could also direct program solutions to resource allocation inequities.

On Guideline Six, Tarrance is convinced that the entire process has been rushed in an attempt to meet an arbitrary deadline. There has not been enough time for the evaluations. Given the controversy and that a general consensus has not developed, the adjustment should not be done without "the most exhaustive study and analysis of the data," which there has not been enough time to do.[76]

On Guideline Seven, Tarrance notes that the Special Advisory Panel met with representatives of the National Conference of State Legislatures. Technicians who must do the redistricting believe that they will be "paralyzed" by the "endless litigation" two sets of numbers will provoke if the census is adjusted,[77] although the very existence of two sets of numbers may be problematic. An adjustment would be most threatening to the creation of redrawn electoral districts for the 1992 elections.

Adjustment, according to Tarrance, will set a precedent for adjusting future censuses. He notes that one person miscounted in the PES represents from 500 to 1,000 persons that would be added or subtracted to develop adjusted numbers. The opportunity for, or perception of, manipulation to achieve desired ends will remain, but once adjustment is routine and not subjected to the scrutiny that it is now, the rigor of public examination to assure that manipulation does not occur will wane, and the risk, therefore increase.[78]

On Guideline Eight, Tarrance states that few people, even expert statisticians, really understand the process being used. He offers several examples of procedures and results of adjustment that are not well understood and states that it is impossible to articulate the complicated statistical procedures to the average person.

Evaluation of Recommendation

I disagree with the implication of Tarrance's discussion of public policy considerations that results of polls should play a substantial role for or against adjustment. I also disagree that if there is consensus that a particular adjustment would improve the counts and consensus that the adjusted counts are better than the enumeration, then an adjustment could be done based solely on that consideration.

I agree with Tarrance's point that there is support for not adjusting because of disruptive consequences for redistricting efforts.

I agree with Tarrance that the seven points of importance he cites, *i.e.,* complexity, lack of accuracy of synthetic estimates, inadequate time for evaluation, two sets of numbers leading to "chaos" for 1992, erosion of trust in census confidentiality, adverse consequences for funding future censuses, and the danger of inside manipulation, are valid expressions of concerns affecting the application of Guidelines One, Three, Six, Seven, and Eight.

I agree with Tarrance's discussions of lack of robustness which occur throughout the discussion. The point is made by him that judgment plays a substantial role in the choice of adjustment procedures. This is a flaw in the adjustment process pointed out in the discussion of Guideline Three, above.

I agree that Guideline One's requirements for accuracy are not met. The problem of misallocating people—even if one counts them correctly at a "higher" geographic level, is raised and documented. I agree that the arbitrariness of outcomes depending upon choice of assumptions is a fundamental weakness of adjustment.

I disagree that two sets of numbers will cause sufficient chaos to make either set not "usable" in Guideline Two terms. This is not the definition of usability intended by the guidelines. In fact, the effects of the numbers, if accurate and usable to the block level, should not play a role in the adjustment decision with respect to Guideline Two. This argument does not raise a bar to adjustment.

I agree that prespecification may be a cause for concern. However, because the prespecifications, such as the decision not to combine demographic analysis and PES results, were professionally done by career Census Bureau staff, I find that they impose no bar to adjustment according to this guideline.

I agree with Tarrance's assertion that adjustment will have an adverse effect on future censuses.

I do not agree that there has not been enough time for the PES evaluations.

I agree with the evidence as cited, including a meeting by the SAP members with representatives of the National Conference of State Legislatures, supporting, anecdotally, a prediction of endless litigation to be engendered by two sets of numbers, if an adjustment is made. I agree that there will be an increasing risk of future manipulation of the counts through adjustments if the precedent is set. This point is acknowledged in the discussion of Guideline Seven, above.

I disagree that the adjustment cannot be explained adequately, should it occur. I believe there is sufficient documentation to do so. I disagree with Tarrance's interpretation of the role of Guideline Eight on this matter.

Recommendation of John W. Tukey

Summary of the Recommendation

Tukey recommends an adjustment. He relies on the same report submitted by and coauthored by Ericksen *et al.* He argues that each and every one of the technical Guidelines are supportive of adjustment and the key Guidelines One and Three are indicative of an adjustment.[79] Tukey addresses the guidelines in the order given here.

On Guideline Four, Tukey states that a decision to adjust will enhance the Bureau's reputation and facilitate future operations, while a decision not to adjust may hinder future census efforts.

Tukey states that the questions raised in Guideline Five have been before the courts several times, and all decisions rendered permit adjustment.

On Guideline Seven, Tukey states that the Guideline must refer to aspects of orderly transfer of political representation that could not be

[75] Tarrance, page 22.
[76] Tarrance, page 27.
[77] Tarrance, page 28.
[78] Tarrance, page 29.
[79] Tukey, page 1.

anticipated in March 1990. There are no such aspects.

On Guideline Eight, Tukey states that the Guideline can easily be met. The technical documentation lying behind the adjustment decision is in keeping with the professional standards of the statistical community.

On Guideline One, in Tukey's professional judgment, the adjustments based on the post-enumeration survey (PES) have been prepared based on the highest professional judgment, and are more accurate, both as to numbers and as to shares, than the raw original enumeration.

On Guideline Two, Tukey notes that, since the Bureau is preparing consistent and complete counts down to the block level, there is "no bar to adjustment." [80]

On Guideline Three, Tukey says that the Bureau has stuck to prespecified procedures. Dr. Robert Fay and consultants Drs. David Hoaglin and Mark Glickman have done a series of studies testing different statistical models that agree with one another and have proved to be good.

On Guideline Six, Tukey states there should be no questions raised about nonadjustment because of inadequate data by 15 July 1991.

Tukey ends with a post-script that notes that the existence of sensitivity of adjustment to reasonable choices should be no bar to adjustment, as long as it is small. The single prespecified procedure produces small sampling errors in comparison with post-stratum to post-stratum differences in adjustment factors to make it clear that adjustment provides smaller combined error than non-adjustment.

Evaluation of Recommendation

I disagree with the assertion that a decision to adjust will enhance the Bureau's reputation or facilitate future census efforts. In fact, other SAP members assert the opposite.[81]

I agree that Guideline Five is not a bar to a decision to adjust.

Tukey's interpretation of Guideline Seven, while unique, would not change the role this Guideline plays in the adjustment decision.

I agree Guideline Eight can be met.

I disagree that the analysis of Guideline One indicates that the Guideline has been met with respect to shares. Since the adjustment must clearly be shown to be superior to the census, controversy over this very important role played by census numbers indicates that the Guideline has, in fact, not been met.[82]

I disagree with Tukey's argument that Guideline Three has been met. In particular, I disagree with his interpretation of the Hoaglin and Glickman study, which he says supports the homogeneity assumption. As noted above, it can be used to support a conclusion that variance is a serious problem with the synthetic estimation model.

I agree that Guideline Six can be met.

I disagree that small differences between alternate sets of adjusted figures are no bar to adjustment, given the requirements to adjust to the block level with distributive accuracy.

Recommendation of Kenneth W. Wachter

Summary of the Recommendation

Wachter recommends against an adjustment. He "conclude[s] that the requirements for accuracy, state and local usability, and robustness articulated in Guidelines One, Two, and Three are not met by the adjusted counts. The broader considerations in Guidelines Four through Eight also, on balance, do not favor a decision to adjust. [He] therefore recommend[s] against adjustment of the 1990 U.S. Census counts." [83]

On Guideline One, Wachter concludes that the adjusted counts are not satisfactory. Although:

> evidence indicates that the adjusted counts are more accurate at the national level, the relative sizes given by adjusted counts are probably less accurate for a number of [S]tates and surely less accurate for a substantial fraction, possibly a majority, of local areas for which [c]ensus counts are to be used." [84]

As a preface to detailed sections on Guideline One, Wachter makes several pages of general observations:

The adjustment of a census is difficult as it is a matter of changing the counts for 6.8 million blocks. A post-enumeration survey (PES)-like survey is usually used to generalize up from sample totals to population totals; for such a use the absolute size of the sample rather than the fraction surveyed would limit the accuracy that could be achieved. The PES is used by the census to generalize down, which is a much more demanding process.

Three things must happen for the PES to be successful. The PES operation must be good, the people missed in the Census have to be reached by the PES, and the reasons why people are missed must be knowable so that one can extrapolate from the people and places analyzed to all the rest, for the PES to improve the census enumeration. The first has happened, the second has not, and the third is in doubt.[85]

The quality of the PES is high. There are problems and limitations but no disasters. Thus the first criterion is met.

A substantial portion of persons missed, net, by the census were not within reach of the PES. Discrepancies between estimates of national undercount between the PES and demographic analysis by age and sex for blacks and non-blacks cannot be explained away by plausible allowances for uncertainty. Half the black males who are missed, net, in the census are being missed, net, in the PES. There is no direct information on the distribution of these people from place to place.

As to the third criterion, the answers are not yet clear-cut. There is insufficient homogeneity at different levels of disaggregation for post stratum for the adjusted numbers to be usable. Erroneous enumerations are numerous and prominent in the adjustment picture. Block level data and district office data do not support the assumption of homogeneity.

Different smoothing procedures should lead to similar answers with respect to adjusted versus enumeration counts, but they do not: they lead to markedly different answers.[86]

Combining census and PES data produces results that are better than either alone only if we know enough about the precision and accuracy of each part. This is an empirical, not an *a priori,* question.

His personal experience with census enumerators and PES enumerators suggests that, contrary to common wisdom, census enumerators may very well have done a better job than PES enumerators in a significant class and number of cases.

> *[He] do[es] not believe that any highly aggregated index or loss function is appropriate for summing up overall accuracy.* It is informative to understand how much the outcomes of calculations with different versions of such aggregated indices differ. But the choice among them is not a scientific choice. Each such index involves implicit value judgments about different sorts of error. For example, each index determines whether a few large errors are more serious than a great many smaller errors. *Whether we agree with a particular tradeoff is a matter of personal and political values. It should not be disguised as science.*[87]

[80] Tukey, page 3.

[81] McGehee, page 6; Tarrance, pages 4–5.

[82] See the discussion in Guideline One above.

[83] Wachter, page 2 of cover letter.

[84] Wachter, page 1, emphasis in the original.

[85] Wachter, pages 1–2.

[86] Wachter, page 3.

[87] Wachter, page 5, emphasis in the original.

The census is the source of small-area data, so accuracy at that level has a special claim although some sensible balance of concern and perspective for level of detail is required.

In the first section devoted to Guideline One, Wachter considers national discrepancies between the PES and demographic analysis. There is a national undercount, although Wachter takes issue with the uncertainty intervals about the point estimates of the undercount. There is also credible evidence of a differential undercount. Although the evidence from the demographic analysis and the PES agree as to the existence of broad differentials, "the evidence as to the pattern by age and sex for blacks and non-blacks does not agree." [88] According to the demographic analysis, a high undercount rate for black adult males, aged 20–64 exists. This does not occur in the PES which means that *"a large portion of the people probably missed by the Census were also missed by the extrapolation from the PES that produced the adjusted counts."* He calls these people "unreachable." [89]

Wachter estimates the numbers of unreachable people to be large, perhaps half-a-million. Since nothing is known about their location, the huge numbers of "unreachable" people mean relative population sizes based on adjusted counts cannot be shown to be more accurate than those based on census counts at any subnational level.[90]

Wachter then turns to patterns in the estimates of net undercounts for post-strata. The patterns of adjustment factors for the 1392 post-stratum groups show regular patterns at higher levels of aggregation, but unexpected complexity when examined stratum by stratum, suggesting heterogeneity where there should be homogeneity. Analysis "for aggregates mask a large amount of diversity within groups, and the story of census coverage, at a level of fine detail, is more complicated than one would hope." [91]

Wachter then turns to the proximate determinants of net undercount. He finds that "erroneous enumerations account for a large portion of the variations in net undercounts across areas and post-strata." [92] Erroneous enumerations play a powerful role in determining the net adjustments to the counts, and this role is masked by smoothing adjustment factors which is probably unjustifiable.[93]

Wachter suggests that variation in erroneous enumeration could be the result of coverage improvement programs. The evidence that can be gleaned from comparing the cities of Detroit and Chicago is mixed. The main conclusion that can be drawn is that "erroneous enumerations are extremely varied. . . . [However,] lumping Detroit and Chicago together in the same post-strata, as the PES does, ignores sizable differences in coverage patterns." [94]

Wachter says that strong correlation between erroneous enumerations and omissions is insufficiently understood, even though it contributes substantially to the size of net undercounts. Since erroneous enumerations exceed omissions in a good number of post-strata, there will be a goodly number of downward adjustment. Thus *"people who themselves filled out their Census forms correctly may be 'minused out' of the Census to compensate for others who were erroneously enumerated"* to calculate an adjustment. "There may be no statistical objection to such a process. But on a human level it is offensive." [95]

Wachter asserts that there remain uncertainties in the demographic analysis, although it has been much improved.

Wachter states that the total error model does not mean all relevant errors for assessing the accuracy of a PES are included. Rather it addresses errors at the level of the evaluation strata only and, furthermore, treats them separately with no joint error structure. There is no simple way to generalize from the evaluation strata to small areas.

The approach is novel, pioneering and controversial. Thus, the "confidence intervals" around error components are not what statisticians usually mean by confidence intervals. The total error model actually estimates only a portion of the possible sources of error in undercount estimates. Components missed are of unknown magnitude. Stratification is applied inconsistently and some of the uncertainty estimates are themselves subject to large uncertainty. The total error model is too optimistic with respect to uncertainties attributed to imputation.

For Wachter, the main lessons drawn from the total error model are that the confidence intervals for most of the non-minority strata are compatible with zero net undercount, but the intervals for all the minority evaluation strata are not. The higher estimated undercounts are subject to high estimated biases.[96]

Several critical aspects of the total error model results are then discussed by Wachter, beginning with correlation bias or "catchability error." The correlation bias assumptions used are not realistic when applied to the PES. People stay out of the Census and the PES not by chance, but because they want to. Dual system estimation depends on chance mechanisms. There are many ways to allocate the twice-missed people. Whether the choice made is good is entirely speculative. How the measurement of variance in the total error model reflects correlation bias is not clear. It is better not to attempt any formal allocation of unreached people to local jurisdictions because of these problems.

Wachter next turns to matching and imputation studies. These studies of matching error give estimates of false non-matches that are too low by the very nature of their design. A small test on step-children illustrates the point that because matchers simply apply rules, they may miss true matches.[97] The effects of imputation may also be larger than the evaluation studies indicate. Wachter uses a sensitivity analysis to indicate the bounds on the effects of imputation. It shows that a great deal rests on the correctness of the assumptions in the imputation, but since these assumptions have not been examined, the measures of variance are too low.

On Guideline Two, Wachter sees "substantial obstacles to using adjusted data for Congressional reapportionment" and concludes that adjustment procedures are not well suited for coping with local heterogeneity in census undercounts. Firm conclusions cannot yet be drawn as to the extent of local heterogeneity and its implications for the accuracy of adjusted local counts.

Wachter shows by example that depending on how imputation is done seats could shift between States in a variety of ways. In estimating adjusted state population counts, adjustment factors based only on within-State data, rather than factors including across state data affect the distribution of Congressional seats as well. Among the five methods tried by Wachter, each apportionment was different and eleven states either gained or lost a seat relative to the census in at least one of the methods.

[88] Wachter, page 9.
[89] Wachter, page 7, emphasis in the original.
[90] Wachter, page 9.
[91] Wachter, page 10.
[92] Wachter, page 11.
[93] Wachter, page 10.
[94] Wachter, page 13.
[95] Wachter, page 14, emphasis in the original.
[96] Wachter, page 17.
[97] Wachter, page 21.

Wachter points out that there is acknowledged lack of homogeneity within post-strata. The issue is whether it is so severe to make adjustment locally infeasible. Very little is known about local heterogeneity. Experiments at the block level give ambiguous results with respect to the balance between improvements and worsenings of counts when adjustments are carried down to the block level. However, Wachter concludes that local heterogeneity is a serious problem for adjusting the counts at district office levels and that perhaps a majority of units could be made worse by an adjustment.

Wachter's experiments and analysis convince him that studies of local-level adjustment have "scarcely begun to scratch the surface" of the issue of how local heterogeneity has an impact on adjustment.[98] His block level analysis leads to more puzzles than answers.

On Guideline Three, Wachter finds that reasonable alternatives to one aspect of the smoothing model lead to significantly different adjustment factors and thus the adjustment factors cannot be considered robust. He finds that smoothing has been the most problematic part of the PES and that the smoothing has had more of an effect on the final adjustment than can be easily justified. The effect of deciding to use pre-smoothed rather than unsmoothed variances in computing smoothed adjustment factors is to raise many adjustment factors by several percentage points, some by more than six percentage points. The changes introduced into the adjustment factors are of the same order of magnitude as the sizes of the adjustment factors themselves.[99] Decisions about pre-smoothing make a large difference and so alternate methods leading to different outcomes seem equally reasonable. In fact, pre-smoothing seems to run the risk of "loading the dice." [100]

Wachter argues that pre-smoothing of variances changes variances in ways that are counter to what one ought to do: reducing large variances increases the weight assigned to empirically unstable factors; increasing small variances reduces the weight assigned to stable factors. In addition, the variance smoothing process is not directed at making covariances more accurate. Furthermore, the choice among regression models is arbitrary in the sense that there is no reason to choose among them, yet the results each set produces differ from one another substantially. Finally, smoothing affects not only adjustment factors, but higher level aggregations of data.

Wachter observes that the effects of the selection of variables for the regression part of smoothing are not negligible but they are not a central issue.

On Guideline Four, Wachter feels that an adjustment would reduce the stake that individuals, civic leaders and Congressional representatives would have in coverage improvement efforts. Adjustment would increase the political leverage of technical decisions and extra efforts to guarantee the Census Bureau's independence and objectivity would be required.

Wachter offers no guidance on Guideline Five.

On Guideline Six, Wachter states that sufficient data are available for a reasoned decision on adjustment.

On Guideline Seven, Wachter says that disruption is likely as a result of an adjustment, but this should not be decisive for the adjustment decision.

On Guideline Eight, Wachter sees no difficulty in meeting professional standards of the scientific community. The details of the adjustment decision tell against its understandability by the general public. Some dismay when an understanding of what adjustment really is should be anticipated, if the decision is to adjust.[101] Adjustment will have victims.[102]

Evaluation of Recommendation

I agree with Wachter's point that the PES, even if it yields results more accurate at the National level, doesn't improve the distribution of population over the results of the census enumeration totals due, in part, to "unreachable" people; among other factors.

I agree with the argument that a good PES is not a sufficient reason to adjust the census. I agree that Wachter's two other conditions are not met, *viz*, people who were missed must be reached, and why they are missed must be knowable.

I agree that Wachter's elaboration of the problem of correlation bias provides insight into why the adjusted counts produced from the PES may be distorted by correlation bias, and not simply underestimate the undercount. There are simply people who are unreachable, and determining why they are unreachable is an insoluble problem.

I agree with the analysis of discrepancies between the PES and demographic analysis.

I agree that the total error model does not include all, or necessarily even most, sources of error. I agree with the criticism that the confidence errors around the components of the model are speculative, and not uncontroversial among statisticians. Pointing out that higher estimated undercounts are subject to higher estimated biases casts serious doubt on the quality of these PES estimates.

I agree when Wachter states that the total error model does not mean all relevant errors for assessing the accuracy of a PES are included. I agree with him as he goes on to say, "Rather it addresses errors at the level of the evaluation strata only and, furthermore, treats them separately with no joint error structure. There is no simple way to generalize from the evaluation strata to small areas. The approach is novel, pioneering and controversial. Thus, the 'confidence intervals' around error components are not what statisticians usually mean by confidence intervals. The total error model actually estimates only a portion of the possible sources of error in undercount estimates. Components missed are of unknown magnitude. Stratification is applied inconsistently and some of the uncertainty estimates are themselves subject to large uncertainty. The total error model is too optimistic with respect to uncertainties attributed to imputation."

I agree with the discussion of Guideline Two that more work is needed to determine the homogeneity problem at the local level.

I agree with Wachter's conclusions with respect to robustness that interpret findings concerning the output from different models as raising questions about robustness at lower levels of disaggregation. In addition, smoothing is correctly identified as a significant factor affecting outcomes for higher level aggregations of data.

Recommendation of Kirk M. Wolter

Summary of Recommendation

Wolter recommends an adjustment. His analysis relies on the joint paper co-authored by Ericksen, Estrada, Tukey, and Wolter. The corrected counts, as required by Guideline One for an adjustment, are more accurate in both level and distribution at the national, state, and local levels.

Wolter finds Guideline One to be the pre-eminent guideline. His conclusion that the corrected counts are more accurate is based first on the observation that the post-enumeration survey (PES) is superior to the census by

[98] Wachter, page 30.
[99] Wachter, page 36.
[100] Wachter, page 37.
[101] Wachter, page 49.
[102] Wachter, page 49.

virtue of the design of matching operations and interviewer training and second, because a survey can be more tightly controlled than a census. The evaluation studies demonstrate that missing data, quality of Census day addresses, fabrication, matching, erroneous enumeration measurement, and balancing sources of error were controlled in the PES to very low levels. Correlation bias, while not so well controlled, is an error such that the PES estimates are still closer to the truth. Random error does not affect the utility of PES estimates.[103]

Wolter's rationale for preferring the adjusted counts includes four major points: (1) PES estimated undercounts agree with expectations and with demographic analysis; (2) the total error analysis demonstrates that corrected counts are more accurate for states, counties, and other similar areas; (3) corrected counts for evaluation strata, which are relatively homogeneous, offer even more improvement than they did for states, especially in comparing five minority with eight non-minority strata and central city versus non central city strata; and (4) if the stratum-level undercount rates are accurate, then the corrected counts for local areas must be an improvement on uncorrected counts.[104] This latter result is based on the Wolter/Causey paper that is appended to the coauthored report as Appendix G. Wolter also cites the plaintiffs co-authored report.

On Guideline Two, Wolter states that the bureau is capable of producing adjusted counts down to the block level, so the first part of the Guideline is satisfied. As to accuracy at small area levels, Wolter notes that, synthetic estimates of the kind used on the 1990 census can improve accuracy at small area levels so long as measured undercounts at aggregate levels tend to have smaller error than the original enumeration at aggregate levels. In support of his position, he again cites the Wolter/Causey paper. The Bureau's P12 study also offers evidence that the adjusted counts are superior to the census counts at the local level.

On Guideline Three, Wolter argues that the PES adjustment procedures were sufficiently prespecified to satisfy the guideline. The three instances where the procedures were not prespecified were "treated with a high degree of objectivity and professionalism."[105] The Hoaglin and Glickman report demonstrates that corrected counts are robust to variations in reasonable alternatives in the smoothing component of the overall PES process. The Census Bureau P1 study demonstrates that the PES undercount estimates are insensitive to differences in the manner of handling missing data.

On Guideline Four, Wolter states that "it is virtually impossible to say anything about the public's cooperation with the 2000 census."[106] The National Opinion Research Center (NORC) study indicates that the average American doesn't understand adjustment, plans to participate in future censuses, and that the adjustment decision, one way or the other, would have little effect. Other countries have instituted adjustment into their censuses with no adverse effect on public participation. Using the most accurate counts is the best way to handle the perception that the adjustment decision is a politically motivated act because Wolter believes that no matter what the decision is—it will be perceived as politically motivated.[107]

On Guideline Five, Wolter acknowledges that he is not a lawyer, but his understanding is that there is no legal ruling that stands in the way of an adjustment.

On Guideline Six, Wolter finds that the necessary data upon which to base the adjustment decision are sufficient, complete and available, and provide a sufficient basis for the adjustment decision.

On Guideline Seven, Wolter finds that the States have been alerted to the possibility of adjusted counts, and can deal with it. The Census Bureau analyses of misapportionment suggests that the original enumeration would misapportion seats more than the adjusted counts. Thus, not adjusting could be viewed as generating more disruption. Wolter is "unaware of any aspect of the 1990 correction process that would cause a truly calamitous disruption of the political process." [108] No part of the correction process has been arbitrary because scientific principles have guided the effort.

On Guideline Eight, in Wolter's view, there is a clear rationale for certifying the correct counts and the Bureau's documentation of the process has been satisfactory. The Bureau and the Department should be able to articulate clearly the basis for the adjustment decision

Evaluation of Recommendation

I do not agree that the PES counts are superior to the census counts. The four points of Wolter's rationale for believing the PES superior are flawed. Contrary to Wolter, PES undercounts do not agree with expectations, or the demographic analysis.[109] For example, the PES misses half a million black males which demographic analysis says are in the population. The total error analysis deals with numeric, not distributive accuracy. Thus, whatever it concludes about accuracy is not to the point of the form of accuracy which must be demonstrated.[110] The homogeneity assumption is in doubt.[111] There is not agreement on the inevitability of increased accuracy at lower levels, notwithstanding a certain degree of accuracy at broader levels.[112]

I do not agree that the synthetic estimate evidence in support of Guideline Two is clearcut, as Wolter states. In particular, P12 casts serious doubt on the homogeneity assumption necessary to a successful synthetic adjustment.[113]

I do not agree with Wolter's interpretation of the evidence with respect to robustness. I believe that the Hoaglin and Glickman report demonstrated that thirteen different models give thirteen different answers. An outcome of that kind is not robustness in the practical sense demanded by this guideline.

I agree that Guidelines Four and Five are no bars to an adjustment decision. On Guideline Six, I note that some panelists feel there is concern that census studies were not sufficiently analyzed in the time frame agreed to in the stipulation and order.

I do not agree that the Census Bureau analyses of misapportionment of Congressional seats are adequate.[114] I do not agree that there is clear consensus that the states can deal with adjusted counts.[115] In my view, while this does not bar adjustment, it remains a consideration to be reckoned with.

[103] Wolter, page 4.
[104] Wolter, pages 4–6.
[105] Wolter, page 9.
[106] Wolter, page 11.
[107] Wolter, page 11.
[108] Wolter, page 15.
[109] See the discussion in Guideline One above.
[110] See the discussion in guideline 1 above.
[111] See Appendix 2.
[112] Wachter, pages 2–3.
[113] See the discussion of distributive accuracy in Guideline One above.
[114] See the discussion in Guideline One above.
[115] See appendix 12.

Recommendation submitted jointly by Eugene P. Ericksen, Leobardo F. Estrada, John W. Tukey and Kirk M. Wolter

Summary of the Report on the 1990 Decennial Census and the Post-Enumeration Survey

The authors begin by considering the enumeration. The census differentially undercounts Blacks, Hispanics, Asians, and Native Americans. The Black undercount has been documented since 1940; the Hispanic since 1980. Differential undercounting is a result of the way the census is taken because it works best for "middle-class suburban" households and worst where living conditions are different. Undercount is strongly negatively correlated with the mailback rate.[116]

The authors state that the original enumeration of the population in 1990 experienced a staggering array of problems. The mail response rate was low, coverage differed between minorities and non-minorities, enumerators gathered less accurate information in cities than in other areas, and nonresponse follow-up operations had a high proportion of last resort and non-data defined responses. The difficulties in enumerating urban areas can be seen from the data. In large city offices 20% of all nonresponse followup was last resort or closeout versus 12% in small city/suburban offices and 11% in rural areas.[117]

The authors claim that last resort and closeout information is incomplete and often inaccurate. More than one-third of all last resort information and 44% of all closeout cases were estimated to be erroneous.[118] Re-enumeration of households originally enumerated by last resort or closeout showed serious errors in certain problem offices. In a national survey of 1,000 one-person hou eholds there was between a 20% and 25% error rate depending on the measure used.[119]

The authors say that coverage improvement programs, while adding people to the count, were frequently in error. For example, more than 630,000 of the 2.1 million persons added through vacant/delete either should not have been added at all or should have been added at a different place. More than half (53%) of the persons added to the count through the parolee/probationer check were estimated to have been added in error. Overall, the coverage improvement programs failed to do what they were supposed to—accurately add a substantial number of persons to the census count and the differential undercount remained after the programs had been completed.[120]

In addition to adding error to the count, the authors argue that the coverage improvement programs failed to find the estimated 19.2 million persons actually missed by the census. The "Were you counted" campaign and the Housing Coverage Check and Local review added only 200,000 and 300,000 persons, respectively, to the count. The low number of accurate additions left intact and possibly increased the differential omission rates by race and type of area that had already existed.[121]

The authors next turn to demographic analysis. Demonstrating through demographic analysis that a black non-black differential undercount exists for every census since 1940, the authors conclude that a black non-black differential undercount exists by virtue of demographic analysis in the 1990 decennial census.[122]

Next, the authors turn to the post-enumeration survey (PES). The PES is the mechanism designed by the Census to determine the extent of, and correction for, census error. The post-enumeration survey has demonstrated the differential undercount of the minority population and solved the major error of the original enumeration, which was the inappropriate shifting of shares of population from areas with many minorities to areas with fewer.

The authors state that the PES was a high quality survey. Completed interviews were obtained 99% of the time for the total PES sample, and for major geographic and racial subgroups. Proxy interviews accounted for 2.4% of the total sample, with little variation in this rate across subgroups. Only 1.5% of the P-sample were unresolved in the matching operation, and only 0.9% of the E-sample. There was little subgroup variation.

The authors use three criteria to evaluate the success of the PES: consistency with expectations of the distribution of the undercount (*i.e.* rates of omission and erroneous enumeration should be higher where census taking was more difficult) and the results of demographic analysis; the P studies (looking at missing data and the outcomes of rematch studies especially); and the possible shifting of population if net undercount rates were altered as a result of the P studies.

The authors state that PES results were consistent with substantive expectations especially when compared with demographic analysis.[123]

The authors' examination of P studies focused on four problems: The effect of variation in assumptions on how to treat missing data; problems due to matching error; problems with census day address misreporting and matching error for movers; and correlation bias. Assumptions about how to treat missing data had little effect. Because the numbers of movers were small, mover matching error had little effect. Correlation bias was a major source of error. Its effect tends to be to reduce estimated undercount. Evidence from evaluation poststrata research shows that adjustment increased the minority share of the nation's population by 0.8%, from 21.4% to 22.2%. The total error model showed a shift of 0.76%.[124]

The next major area considered by the authors was the smoothing of the adjustment factors. They consulted with David Hoaglin to evaluate the impact of the decisions on carrier variable choice, how to smooth variances and covariances of raw adjustment factors before calculating the regression, and how to weight individual observations when calculating the regression.

Hoaglin identified how to smooth the variances before using them to weight observations in the regression calculations and how to smooth the covariances before using them for the same purpose as key decisions.

Hoaglin fitted thirteen different regressions. The first nine were based on three strategies for smoothing variances and three strategies for smoothing covariances ($3 \times 3 = 9$); a tenth alternative was suggested by a Panel member; finally for comparison purposes he considered equal weighting of observations; weighting according to raw variances and covariances; and weighting according to raw variances, replacing the covariances by zero.[125]

After considering various alternative "stopping rules" for the "best subsets regression," Hoaglin chose a "back-2" stopping rule which uses apparently the best subset among those involving two fewer carrier variables than are in the set that minimizes the ratio residual mean square/residual degrees of freedom.

Hoaglin used two strategies to test whether the decisions had serious impact on the estimates: The first strategy used the difference in fitted values from each pair among the 13 choices and differences between the 13

[116] Ericksen, *et al.*, pages 1–2.
[117] Ericksen, *et al.*, pages 4–5.
[118] Ericksen, *et al.*, page 6.
[119] Ericksen, *et al.*, page 6.
[120] Ericksen, *et al.*, pages 7–8.
[121] Ericksen, *et al.*, page 8.
[122] Ericksen, *et al.*, pages 10–11.
[123] Ericksen, et al., pages 13–14.
[124] Ericksen, et al., pages 12–16.
[125] Ericksen, *et al.*, page 18.

and the Bureau's regression fit; while the second strategy used the reallocation of population shares among the 13 evaluative post strata.

Hoaglin stated that alternative smoothing models produced estimated population share gains for minorities that closely "surround the Bureau fit," ranging from 0.48% to 0.77%[126]

Next the authors considered errors for large and small areas. In looking at the differences in errors for large and small areas, they concluded that the total combined error increases as the size of the group decreases (*e.g.*, the combined errors for 5 million blocks will be larger than the combined errors for 1,392 poststrata), and consequently the improvement in amount due to adjustment would be nearly the same for larger and smaller groups—the improvement in percentage terms decreases, but does not change sign, as the groups become smaller.

The authors stated that since the expected CV for a sampling stratum is 1.4%, they were more likely to expect improvements for those areas where undercounts are especially high or especially low. It is these extreme cases where most of the benefit of adjustment is to be expected. Improvements in quite large areas thus prophesies improvements in very small areas, as well as in intermediate areas.

The authors' major conclusions are that error in the uncorrected census was very high; this error disproportionately affected Blacks, Hispanics, Asians and Native Americans; and the PES derived data can be used to correct the census and substantially reduce the differential undercount and improve accuracy at both national and local levels.

Evaluation of the Report on the 1990 Decennial Census and the Post-Enumeration Survey

I do not find the discussion of the quality of the census relevant. Guideline One stipulates that the census is the standard. Thus, irrespective of the flaws in the census, Guideline One precludes adjustment unless the adjustment is shown to be better than the census by convincing evidence.

I do not agree with the statements in discussions of the PES claiming that PES results were consistent with expectations when compared to demographic analysis is made. There were sizable, and unexpected differences between the PES and demographic analysis which indicate that a PES based adjustment would be inadequate. [127]

I do not agree with the interpretation of the Hoaglin materials. The authors' interpretation misses the point. The issue is not whether the thirteen different outcomes fluctuated around a Bureau estimate of "truth" derived from the PES and are thereby defined as demonstrating sufficient robustness. The very fact of such a variety of outcomes is precisely the lack of robustness that is of concern when using a model based synthetic adjustment at a low level of geography.

The authors state that the expected CV for a sampling stratum was 1.4%. The expected CV was .7%.

I do not agree that PES derived data can be used to correct the census and substantially reduce the differential undercount and improve accuracy at both national and state levels. [128]

SECTION 4—DECENNIAL CENSUS PROCEDURES

In this section I provide documentation for the procedures used to conduct the decennial census, the post-enumeration survey, the evaluation of the post-enumeration survey, and the evaluation of the demographic analysis. Additional information on the post-enumeration survey evaluation program and demographic analysis will be found in appendix 3.

1990 Census of Population and Housing: The Bicentennial Census of the United States

Planning for the 1990 Census began in 1984, with planning activities, testing, and preparatory operations occupying the remainder of the decade. Data were collected in 1990, and, as required by law, State population and apportionment totals were delivered to the President on December 26, 1990. The total population count transmitted to the President was 249,632,692, composed of a resident population of 248,709,873 and an overseas population of 922,819.

The Census Bureau was also required by law to deliver redistricting counts and maps to State redistricting officials no later than April 1, 1991. This was done. While the Census Bureau met its two legal mandates for the delivery of apportionment and redistricting data—two of the most important uses of census data—the 1990 census is not considered completed until all planned census data products have been released. Final products will be released in 1993.

The 1990 census involved enumerating 249,632,692 people in more than 100 million housing units, and collecting a full range of characteristics about each person. Extensive planning and preparation, the successful recruitment and employment of hundreds of thousands of temporary census workers, and an automated management information system to keep track of operations were required to complete the census on time and within budget.

Planning and Preparation

The Census Bureau designed the 1990 census keeping in mind the special problems that arise in the census-taking process, as well as constraints of time, budget, and the need to protect individual confidentiality. Plans incorporated the lessons learned from previous censuses. The plans were tailored to implementation and management by a temporary work force in a compressed time frame. Extensive testing was conducted so that hard evidence could be gathered on the utility of new procedures and techniques. The testing also allowed new procedures and techniques to be refined and adjusted.

Formal planning for the 1990 census began in FY 1984. This early start allowed the Bureau to begin major testing of proposed design features earlier for the 1990 census than for the 1980 census (1984 *vs* 1976), and to conduct more major tests of proposed features than for prior censuses (e.g., 7 for 1990 *vs* 5 for 1980). Improvements were made in every phase of census-taking. Some were aimed directly at overcoming operational, control, and timeliness problems identified in 1980 census operations. Others were intended to increase the cooperation of hard-to-enumerate groups. These improvements are described in detail in "Planned Improvements in the Counts for the 1990 Census," April 1989, Bureau of the Census. Improvements included:

- An expanded promotion campaign aimed at hard-to-enumerate groups. For example, for the first time, the Bureau used minority advertising campaigns designed by minority firms, in addition to a more traditional general-audience campaign.
- More cooperation between the Census Bureau and state and local governments. For example, the Census Bureau improved and expanded the Local Review Program, which gives local officials an opportunity to review census counts, by providing training on how to participate in the program, and by instituting two phases of review instead of one, as was the case for the 1980 census.
- Efforts intended to make it easier for people to respond to census questionnaires. For example, the Bureau expanded questionnaire assistance operations for 1990 by offering toll-free

[126] Ericksen, et al., pages 17–19.

[127] See the discussion in Guideline One above.

[128] See the discussion in Guideline One above, where the deficiencies in distributive accuracy of an adjusted count, using Census Bureau procedures, are detailed.

telephone assistance in English, in Spanish, and in six Asian languages, and by sending out multilingual "early alert" flyers about the census in selected areas.

• Tailoring census procedures to deal with special or unusual situations. For example, enumerators delivered questionnaires to public housing developments, and the Bureau hired public housing residents to deliver the questionnaires and conduct outreach activities at the same time.

• A greatly increased amount of automation in the census. For example, an automated management information system, in conjunction with an automated address control file, enabled home office control and monitoring of the 1990 census to deal with developing problems early and rapidly.

• Implementing an automated geographic control system—called TIGER—in cooperation with the U.S. Geological Survey. The TIGER System solved one of the most serious problems of the 1980 census—late, inconsistent, and illegible maps. The TIGER System assured accurate and timely maps and geographic files for the 1990 census.

The 1988 dress rehearsal was the capstone of planning efforts; it was preceded by 5 years of consultation with data users and formal tests of alternative procedures and questionnaire content of the kind just described. The Bureau consulted with a wide range of data users, including minority organizations, planners and academics, business leaders, representatives of private organizations, state and local officials, and Federal agencies.

Once the basic plan for the census, including improvements, was determined, the Census Bureau began to prepare for 1990 data collection and processing. These preparations included map-making, questionnaire printing, address list construction, setting up a field structure of over 500 offices for data collection and processing, procuring and installing automated equipment, and preparing promotion materials.

A critical activity was preparation of a precensus address list. This list was used to determine which housing units had or had not returned a questionnaire in areas where householders were instructed to return their questionnaires by mail. In all, some 100 million addresses were compiled before the census from purchased lists, field canvassing by census enumerators, and a series of overlapping checks and update operations by census workers, the U.S. Postal Service, and review by local officials.

By March 1990, all preparatory activities had been completed and the data collection phase of the census, which involved attempting to get a completed questionnaire for every person and housing unit in the Nation, was set to begin. (Enumeration of remote areas of Alaska had begun a few weeks earlier in order to complete the enumeration before the Spring thaw.)

Basic Enumeration Procedures

The 1990 census was planned to be a multiphase and incremental process that was to determine the population as of April 1, 1990. Except for remote areas of Alaska, questionnaire delivery or mail-out occurred in March 1990, but the enumeration was not intended to be over then. The Census Bureau built into the census process programs to follow up on housing units that did not return a questionnaire and to ensure that every reasonable effort was made to enumerate every housing unit. These programs extended well after April, into the fall of 1990.

90 percent of the housing units were expected to complete questionnaires and return them by mail. Two procedures were used in such mail-back areas—mail-out/mail-back and update/leave.

For the remaining housing units, householders were instructed to hold their completed questionnaires for enumerator pick-up. This procedure was called list-enumerate. Other special procedures were designed to enumerate persons who lived in group quarters (such as college dormitories and military barracks) and persons who had no usual residence.

Mail-Back Areas

Mail-Out/Mail-Back

The mail-out/mail-back procedure was used for large cities, suburban areas, and some smaller cities, towns, and rural areas where mailing addresses were house number and street name. In all, about 83 percent of U.S. housing units were in mail-out/mail-back areas. Mail carriers in these areas delivered addressed questionnaires on March 23, 1990, and householders were asked to mail back completed questionnaires by April 1, 1990. Five out of six housing units received a short form containing *only* the questions asked of all housing units; one out of six housing units received a long form with additional questions. One week after mail-out, a post card was sent to each housing unit reminding persons to fill out the questionnaire and return it as soon as possible. This was in addition to the multiple-component promotion campaign, then at its peak.

The USPS returned some questionnaires to the Census Bureau as "undeliverable." The Bureau added a special operation to have census enumerators deliver by hand as many of the "undeliverables" as possible. The remaining housing units did not receive a mailing piece at this time, so they were enumerated during nonresponse follow-up (see below).

Update/Leave

The update/leave method was used in rural areas in the South, Midwest, and Appalachia, where mailing addresses are rural-route designations, or where many householders pick up their mail at lock-boxes. These areas contain about 11 percent of the housing units in the Nation. Here, census enumerators, rather than the USPS, delivered the census questionnaires and, at the same time, updated the address list. This operation began in early March 1990 and continued throughout that month. Just as in mail-out/mail-back areas, householders in update/leave areas were to complete and mail back their questionnaires by April 1, 1990. Again, most units received a short form, but a small pre-designated sample received the long form. Householders in these areas also received a reminder postcard asking them to return their questionnaires.

List/Enumerate

The list/enumerate, or door-to-door method, was used for about 6 percent of the Nation's housing units. These units were primarily in very remote and sparsely settled areas. There was no precensus address list for these areas. Mail carriers delivered unaddressed short-form questionnaires on March 23 and, beginning about April 1, census enumerators went door-to-door listing addresses, picking up completed questionnaires or filling out questionnaires as necessary, and administering the long form at a sample of these units.

Special Procedures

Special place enumeration took place in March and April, 1990. Special places include group quarters, such as boarding houses, nursing homes, dormitories, rectories, convents, hospitals, etc. Enumerators visited these places to collect information from each resident. About 2 weeks before Census Day, the Census Bureau also conducted a Street and Shelter enumeration (S-night) to collect information from components of the homeless population. The first phase

of this operation focused on enumerating persons staying in shelters for the homeless, while the second phase focused on enumerating homeless persons living outside of shelters, for example, on the street.

There were two additional components of special place enumeration: Transient enumeration and military enumeration.

- During transient enumeration, census workers visited travel places where guests are unlikely to have been reported at their usual place of residence, or where guests are unlikely to have a permanent residence. These places include YMCA's, YWCA's, youth hostels, commercial campgrounds, etc.
- For military enumeration, special procedures were used to count domestic military and maritime personnel. Military bases and vessels were self-enumerating. In these instances, bases appointed a senior commissioned officer to serve as the enumeration project officer.

Questionnaire Receipt

Some households received a short questionnaire containing only the questions asked of all households, while others received a long form containing additional questions. About 17 percent (or a sampling rate of about 1-in-6) of the households received the long form. However, in places with an estimated 1988 population of less than 2,500, the sampling rate was 1-in-2. Based also on precensus estimates, very populous census blocks had a sampling rate of 1-in-8. All other areas had a sampling rate of 1-in-6.

Once questionnaires had been delivered, forms began to arrive by mail in district or processing offices serving each area. Mail returns for some areas went to a processing office for check-in. For most areas, mail returns, as well as questionnaires completed by enumerators during list/enumeration or special place enumeration, went directly to a district office. Both processing offices and district offices used automated equipment to check in forms by bar code scanning of the return envelope. The associated address in the automated address control file was then coded to show that a questionnaire had been received for that unit. At the conclusion of the check-in phase, each listing not coded represented a case that would have to be visited by an enumerator during nonresponse follow-up.

Nonresponse Follow-up

The Census Bureau followed up every housing unit for which a questionnaire was not returned. Daily reports on the mail return check-in rates for each district office were transmitted to headquarters through the automated management information system. This information was used to project the likely workloads for nonresponse follow-up. This overall workload was expected to require over 250,000 temporary enumerators to visit 30 million units over a 2 month-period. By the end of April, the Census Bureau had to estimate the number of persons it needed to hire, and to begin preparing lists of addresses that had not returned a questionnaire. The mail response rate was 63 percent, lower than the projected 70 percent. As a result of this, the Census Bureau hired more enumerators than it had originally planned for nonresponse follow-up.

The Census Bureau completed nonresponse follow-up for the 1990 census substantially earlier than had been the case for the 1980 census, despite a larger workload. Recruitment goals were met despite the need for more workers engendered by the low mail response rate, and in spite of lower levels of general workforce unemployment than had been the case for the 1980 census.

During nonresponse follow-up, enumerators were required to make up to six attempts to contact a household member and complete a census questionnaire. If this was not possible after three personal visits and three telephone calls at different times and on different days, the enumerator attempted to obtain at least basic information on household member(s) from knowledgeable sources, such as neighbors or building managers.

Because the nonresponse follow-up had to be completed quickly so that other operations could be conducted, each district office was authorized to begin a final phase of nonresponse follow-up once 95 percent or so of the operation had been completed. During this phase, enumerators made one more visit to each remaining case to obtain as complete an interview as possible.

Coverage Improvement Efforts

Basic data collection activities included various steps designed to improve census coverage. Among these were special promotion and outreach efforts, better address listing procedures, extra efforts to increase mail returns, follow-up on all housing units that did not return a questionnaire, better management of and pay for enumerators, etc. But after basic data collection, census plans also included additional special programs to improve the population count that went beyond standard procedures.

These additional coverage improvement programs, which represent the Census Bureau's policy of giving everyone several opportunities to be included in the census counts, added about 5.4 million persons to the census counts, or about 2.2 percent of the total enumerated population.

Such coverage improvement programs included: (1) The 100-percent recheck of vacant housing units or those identified as uninhabitable or nonexistent; (2) the "Were You Counted?" campaign, an opportunity for people who thought they might have been missed to call in or fill out a census form printed in the newspaper; (3) the parolee and probationer check, which involved working with parole and probation officers to get names and Census Day addresses of parolees and probationers and add them to the census had they not already been counted; (4) the housing coverage check, in which the Census Bureau recanvassed selected blocks based on evidence brought to its attention by the automated management information system; and (5) the postcensus phase of the local government review program.

Recheck of Vacant Housing Units and Those Identified as Uninhabitable or Nonexistent

During the follow-up of nonrespondents by enumerators in May through July, some housing units were identified as vacant or uninhabitable; some addresses were added to the address control file. Each of these units was rechecked by another enumerator in July or August.

Of the approximate 8 million vacancies, the recheck showed 7.6 percent had been occupied as of Census Day, April 1. Their occupants were enumerated at the time of the recheck. This added about 1.6 million persons to the count. Of the approximate 2.9 million units previously identified as uninhabitable or nonexistent, 5.4 percent were reinstated as occupied April 1. These conversions added almost one-half million persons to the count.

"Were You Counted?" Campaign

After the primary data collection, the Census Bureau initiated a procedure to give anyone who thought he/she had been missed the opportunity to fill out publicly available forms or call toll-free 800 numbers that operated in English, Spanish, and six Asian languages. Communities, the media, and many of the 56,000 community-based organizations that had helped initially promote answering the census were encouraged to conduct "Were You

Counted?" campaigns, reproduce census-designed forms or promote call-ins to the 800 numbers. The purpose of the campaign was to give a second chance to those who might initially have avoided being counted, or to reach persons not part of the principal family in a household who might not have been listed on the household questionnaire. Initially, the Census Bureau planned to end the campaign by June 30, 1990, but because so many organizations participated, the toll-free numbers were held open until September 30.

In all, about 400,000 "Were You Counted?" calls or forms came into the Census Bureau. Although the majority of these proved to be persons who had already been counted, the forms did add over 200,000 persons to the census.

Parolee and Probationer Count Check

Research had suggested that a group with a high probability of having been missed in prior censuses were those on parole or probation, a group consisting disproportionately of young males. Thus, in February 1990 the Census Bureau sent letters to the governors and heads of correction departments in each state and the District of Columbia asking them to participate in a program to get parolees and probationers counted. Each was asked to name a liaison to handle the program. Each liaison was sent special individual forms to distribute to their parole and probation officers, who in turn were to distribute them to those under their jurisdiction.

The response rate for the program was disappointingly low—so low in fact, that the Census Bureau sent enumerators to work with parole and probation officers to complete a form for each parolee/probationer with a verified April 1 address. As a result of this activity, it is estimated over 400,000 persons were added to the census.

Housing Coverage Check

With a computerized census that captured questionnaire data as returns came in, it was possible to make additional accuracy checks not possible in prior censuses. In August of 1990, the Census Bureau searched its data bases to identify any blocks or communities for indications of a low count. While the census was still in progress there was time for a further canvass to make corrections. Population and housing counts, which had accrued thus far for the 39,189 units of local governments, were compared with 1980 counts and recent population estimates. The Census Bureau looked at its data on areas of new construction for possible missed new subdivisions. It also searched to see if the "Were You Counted?" forms showed any pockets of housing that might have been missed. It looked at media reports or local complaints of missed buildings or blocks. Based on these data searches, the Census Bureau decided to recanvass blocks where problems might exist. These blocks represented 15 percent of the Nation's housing units.

Postcensus Local Government Review

39,189 units of local government were sent housing counts and group quarters counts, accrued as of mid-August, to compare with local data. (New updated maps for the communities had already been sent to them in July). Governments were given 15 working days in which to challenge the housing unit or group quarters count for any block. The feedback from local governments was varied. Many took the counts to be final, although the Vacancy Recheck, the Housing Coverage Check—in fact all of the coverage improvement projects done after the primary data collection—were still in progress. All in all, 17 percent of local governments, including all of the 51 largest cities, challenged some blocks, and eight cities challenged over 2,000 blocks. Cities that challenged more than 2,000 blocks in Postcensus Local Review were Atlanta, Boston, Chicago, Detroit, Honolulu, Los Angeles, New York, and Philadelphia.

The recanvass generated by the Housing Coverage Check and Local Government Review yielded new housing units that added over 300,000 persons to the final census count.

The 1990 Post-Enumeration Survey (PES)

Background

The Census Bureau used two major programs to measure coverage for the 1990 census. The first was the Post-Enumeration Survey (PES), which was an independent survey taken after the census and then compared to the census to attempt to measure coverage error in the census. The second program was Demographic Analysis (DA). DA produced an independent estimate of total population by combining information from various sources of administrative data. The process included using historical data on births, deaths, and legal immigration combined with estimates of emigration, undocumented immigration, and Medicare information. Estimates of total population from DA were then compared with census counts to get an estimate of coverage error.

Summary

The PES was a check of the census but not a recount. After the census, interviewers returned to the field to identify all persons living in the sample of blocks at the time of the PES. During the interview, the interviewer asked where each person was living on Census Day—April 1, 1990. This information was then matched to actual census questionnaires. Most people on the PES questionnaires matched to the census. Some did not, and these are the people estimated to have been missed in the actual census. This part of the PES was called the P-sample. People estimated to be missed based on the P-sample were estimated gross omissions in the census.

People can also be included in the census erroneously. An erroneous census enumeration, for example, could be a child born after April 1, 1990, a person who died before April 1, or a college student away from home who was enumerated at his or her parents' address instead of being correctly enumerated at his or her college. Erroneous enumerations also include persons counted twice in the census. Gross erroneous inclusions in the census were measured in the same blocks as the PES and were called the E-sample.

The data on gross erroneous inclusions and gross erroneous omissions were used to produce an estimate of the net undercount or net overcount of the population in the census. This process is described in the following paragraphs. [1]

Selecting the Sample (Sample Design)

The census attempted to cover all people and was conducted in all blocks. The PES was a sample. The PES sample was selected in stages. First a random sample of blocks was chosen. Within sample blocks, all housing units were interviewed. Within an interviewed housing unit, a PES interview was conducted for each person.

Since the PES was a sample, if total population estimates were to be calculated based on it, the results had to be generalized to other people not living in sample blocks. One statistical method to improve the accuracy of this generalization process was to classify sample cases into groups (called post-strata) such that within a group, people were as alike as possible with regard to their propensity to be undercounted. Ancillary evidence indicates that undercoverage is worse for males than

[1] For a more detailed discussion of PES see Howard Hogan, "The 1990 Post-Enumeration Survey: An Overview," a paper presented at the American Statistical Association in August 1990.

females; for minorities than non-minorities; for renters than owners, etc. Therefore, these types of characteristics were used to define the post-strata. The Bureau did not know which post-stratum to assign a person to until after the PES interview was conducted. To help insure an appropriate sample size by post-stratum, the blocks in the U.S. were stratified by similar characteristics before selecting the sample blocks from them.

All blocks in the United States were assigned to one of 101 strata. The strata were defined by geography, city size, racial composition, and percent renter. A representative set of blocks was selected from each stratum. A separate sampling stratum was defined for American Indian Reservations.

Persons living in institutions were excluded from the PES, as were military personnel living in barracks, people living in remote rural Alaska, persons in emergency shelters and persons who had no formal shelter. For each of these categories, it was unreasonable to expect to be able to conduct an independent interview in July and match them to their April 1 location.

The eventual PES sample consisted of about 168,794 housing units in 5,290 block clusters that included 12,124 blocks. (See attachment 1, "PES Sample Size by State.")

The sample was designed to achieve a .7 percent coefficient of variation. That is, the level of sampling error was expected to be .7 percent of the level of estimated undercount or overcount. So for example, if the PES estimated the undercount to be 5 percent, it was expected that the sampling error (or margin of error) on that estimate would be .35 percent. In practice, the sampling error was, on average, 1.7 times more than anticipated by the sample design.

Listing and Enumerating

In February 1990, permanent interviewers of the Census Bureau visited each of the sample blocks to list all housing units they contained. To preserve independence, none of the temporary enumerators hired to take the 1990 census was used for this operation; nor was the listing conducted out of the temporary census offices. To maintain independence, the Census Bureau did not want anyone to know where a PES sample block was so that it would be treated differently during the census.

After the completion of the 1990 census follow-up of those housing units that did not return a questionnaire (called nonresponse follow-up), a set of PES enumerators interviewed persons at households in the PES sample blocks. Although this interviewing drew from enumerators who had worked on 1990 census follow-up, steps were taken to preserve independence, such as not allowing an enumerator to work in a block in the PES that he or she had worked in during the census.

The interviewers determined who was living in each housing unit, obtained their characteristics, and asked where they lived on April 1, 1990, Census Day. The PES interviewing began nearly 3 months after Census Day. Many people had moved during that time. In order to determine whether they were enumerated in the census, the Bureau needed to know where they lived on Census Day and, thus, enumerators asked a series of probing questions to determine occupants' Census Day addresses.

There was a quality assurance program for the interviewing phase to ensure that the interviewers really visited the household and that the people listed were indeed real. If interviewers made up people, they would not match to the census and would inflate the undercount rate.

Matching

The next step was to match the persons enumerated during the PES (the P-sample) to the census. The matching operation was the first step in determining whether persons in the P-sample were enumerated by the census or missed. Basically those persons in the P-sample matched to the census were considered to have been enumerated; those nonmatched were considered to have been missed.

Matching was carried out in four stages. It involved an initial stage of computer matching followed by two stages of clerical matching to attempt to resolve cases that the computer could not match. The two stages of clerical matching were differentiated by the level of skill and judgment required to establish a match.

Those persons in the P-sample not matched to the census by computer and the first two stages of clerical matching were assigned for a follow-up interview, if it was determined that additional information was necessary to establish whether a match to the census was appropriate. An additional fourth stage of clerical matching was then conducted that allowed the more skilled clerical matchers to use the information from the follow-up interview to establish additional matches.

First, the matching classified people as included in the census only if they were counted at the address where they should have been counted, according to the information they provided. This concept was called "correct address" matching. For example, census rules required that a college student be enumerated at the university dormitory, not at his/her parents' home. The PES counted the student as "enumerated" only if he/she was counted at the university. If he/she was not counted at the university, then the student was classified as "omitted" even if he/she were counted at home. In order for the estimation to work out, the enumeration at home was classified as erroneous and subtracted from the census. So in this example, there would have been one omission (at the university) and one erroneous enumeration (at home). The two netted out in the aggregate. The decision to use "correct address" matching was not lightly taken. Indeed, some earlier tests used "any address" matching, i.e., attempting to search all reported addresses. Either approach has advantages and disadvantages.

The second concept was that of the search area. If a person reported that he lived at a given address, then the matching classified him as correctly enumerated if he was counted anywhere in the block. It also classified him as correctly enumerated if he was counted in a surrounding block. There was a limit to how far the matching process could search. If a census computer operation coded the address across town, for example NW vs. SE, the matching did not search there and did not find the person. The matching counted him/her as missed. To balance, the system had to count the other enumeration as erroneous, because it was outside the defined search area.

A final concept was the idea of "sufficient information for matching." When a match was found, it was easy to say that the case was enumerated. When no match was found, it did not necessarily prove that the person was not enumerated, but merely that the search had not been conducted in the correct place. A further review of the case might have shown that there was "insufficient information," leading to its being classified as "unresolved." Rules that classify cases as "sufficient information for matching" were applied before the matching begins. These rules were designed so that for matches there was confidence that the person was correctly enumerated and, equally important, for non-matches, there was confidence that the person was omitted. This approach leads to a somewhat higher "unresolved" rate, but presumably to more accurate overall results.

The accuracy and consistency of the matching process were central to the PES process. Too many matches would

have decreased the estimate of population, too few would have increased it. Matching errors would have distorted the estimated population distribution if they differed by post-strata. The rules were developed over a decade of research. The multiple levels of matching were designed to ensure that the rules were applied consistently between clerks and between offices.

The E-sample, those persons in the PES blocks who were enumerated in the census, was examined to determine if they were correctly enumerated. E-sample persons were matched back into the census to determine if they were enumerated more than once (duplicates). E-sample persons who were matched to the P-sample were assumed to be correctly enumerated (except for duplicate census enumerations). The remaining E-sample persons who were not matched to the P-sample were potential candidates for erroneous enumerations. These unmatched census persons were also included in the PES follow-up operation described above. The follow-up interviewers determined the enumeration status of those persons; that is, if they were correctly enumerated and simply not in the P-sample or if they were erroneously enumerated.

Errors in measuring census erroneous enumerations have almost as much effect on the final estimate of net undercount as errors in measuring census omissions. Reinterview and rematch studies were used to measure the error that the PES makes in measuring census erroneous enumerations and the effects of these errors on the PES estimates.

In processing the E-sample, it was important to include all census enumerations, especially those conducted long after April 1. Common sense and the results from 1980 both indicated that these were more likely to be erroneous than those done on or near April 1. Because of this, there was a special operation to process census enumerations that were enumerated late in the census process. This operation presented special challenges in merging the data with the results of the earlier operation and completing the processing in time.

A final matching and reconciliation operation took place at the conclusion of the PES follow-up. This included the fourth stage of clerical matching for the P-sample and a determination of whether persons in the E-sample were correctly or erroneously enumerated. An important aspect of this operation was that situations arose where correct match status for persons in the P-sample, or correct enumeration status for persons in the E-sample, could not be determined. This situation occurred because the initial interview was inconclusive or because an incomplete interview was obtained during the follow-up.

Imputation and Dual System Estimation

A final PES file was created that reflected the results of the operations described above. This file included the characteristics of each person in the P-sample and the E-sample. The file also included the match status for persons in the P-sample and the enumeration status (correct or erroneous) for persons in the E-sample. As the final file was prepared, computer editing or imputation was performed to correct, insofar as possible, for missing or contradictory data. A critical aspect of imputation involved the estimation of a final match status for those persons whose match status could not otherwise be resolved. The estimation of match status was very critical. For example, mistakes in the PES matching process, which incorrectly identified persons as not counted in the census (nonmatches), erroneously overstated the estimated undercount and vice versa.

The data in the final PES file were then summarized and incorporated with data from the full census to produce dual system (PES and census) estimates (DSE's) of total population. The DSE's were produced for unique estimation strata (or groupings of persons described below). The dual system estimator is explained more fully in Hogan's document cited above. Essentially it involves estimating how many people were (1) in the PES and in the census, (2) in the PES and out of the census, (3) in the census but not in the PES, and (4) in neither the census nor PES.

The dual system model conceptualized each person as either in or not in the census enumeration, as well as either in or not in the PES. Each person was classified according to the following tableau where the subscripts denote row and column and the stars indicate summing over the entire row/column. N_{**} denotes the entire population.

ENUMERATION

PES	Total	In	Out
Total	N_{**}	N_{*1}	N_{*2}
In	N_{1*}	N_{11}	N_{12}
Out	N_{2*}	N_{21}	N_{22}

All cells were conceptually observable except for N_{22}, and of course any of the marginal totals that include N_{22}. The cell N_{22} (often called the 4th cell) was an estimate of people missed in both the census and the PES. Even though not directly observable, the DSE of total population included an estimate of people in the 4th cell. The DSE of total population was based on several assumptions. If the PES was an (approximately) unbiased sample of the whole population, then an (approximately) unbiased estimate of N_{**} could be made by noting that the ratio of those in the PES and in the census to the total in the PES should have been the same as the ratio of the total in the census to the total population. Algebraically:

$$N_{11}/N_{1*}=N_{*1}/N_{**}$$

Then solve for the total population:

$$N_{**}=(N_{*1}\cdot N_{1*})/N_{11}$$

This is the dual system estimator of total population.

DSE's were prepared in each of 1,392 post-strata (see next section for a description). Knowing the undercount or overcount rate for each of the groups was important for estimating the net undercount at the local level. It was acceptable for both the PES and the census to have different coverage rates for different post-strata. However, if within a post-stratum, there were subgroups where both the PES and the census had significantly lower coverage, then the DSE would have been biased.

Another type of bias would have arisen if being enumerated in the census affected the person's response to the PES, or being in the PES affected the person's response to the census enumeration. This would be the case if the PES interviewer and the enumerator compared notes, or if a person refused to cooperate in the census because he had been recently interviewed in PES. The design sought to minimize this effect by conducting the PES after most of the census operations were completed and by conducting the PES out of the Regional Census Centers rather than out of the local District Offices that conducted the enumeration.

Post-Strata

Using the match status and key data, such as age, race, and sex for each person in the sample, the Bureau prepared DSE's of the total population for each of 1,392 groupings of people (post-strata). The reason for forming the post-strata was to group persons who had similar chances of being enumerated in the census. The post-strata were defined by census division, geographic subdivisions such as central

cities of large metropolitan statistical areas, whether the person was the owner or renter of the housing unit, race, age, and sex. Each person in the PES sample belonged in one of the unique post-strata. A full description of the 1,392 post-strata is shown in attachment 2.

For purposes of illustration, the following are examples of the 1,392 post-strata. One example is a post-stratum which contains Black males, age 20–29, living in rented housing in central cities in the New York primary metropolitan statistical area. A second example is that which contains non-Black non-Hispanic females, age 45–64, living in owned or rented housing in a non-metropolitan place of 10,000 or more population in the Mountain Division. A third example is that which contains Asian males, age 45–64, living in owned or rented housing in metropolitan statistical areas but not in a central city in the Pacific Division. A fourth example is that which contains non-black Hispanic females, age 30–44, living in owned or rented housing in central cities in the Los Angeles-Long Beach primary metropolitan statistical area or other central cities in metropolitan statistical areas in the Pacific Region. As can be seen from these examples, the 1,392 post-strata are very specific.

The Decision on Combining PES and DA Results Before Computing Adjustment Factors

It was expected that the estimate of total population from the PES would be lower than the estimate of total population from DA. That is because there is a tendency for some people to be missed in both the census and the PES. (often referred to as correlation bias.) No such bias exists with DA estimates. For that reason, there was an open decision point about whether or not to "rake" PES estimates to DA estimates before producing adjustment factors.

After examining the information, the Census Bureau decided against trying to combine the results of DA and PES. There were several reasons for the decision. Some of the main ones include:

- The PES estimate of total population was higher than the DA estimate.
- The PES estimate of females was considerably higher than the DA estimate.
- At the point in time the decision had to be made, the DA estimates were preliminary. There was concern that DA estimates might change considerably over time.
- A concern about the quality of certain components of the DA estimates; for example, the estimate of undocumented immigrants.
- The uncertainty about how combining DA estimates might effect the assumptions underlying the DSE system.

Adjustment Factors

The next step in the post-enumeration survey process was to compare the estimated total population for each post-stratum (the dual system estimate or DSE) to the census count to determine a "raw" adjustment factor. For example, if the DSE for a particular post-stratum was 1,050,000 and the census count was 1,000,000, then the adjustment factor was 1.05, reflecting about a 5-percent estimated net undercount of variability. An adjustment factor may be less than one, thus lowering the census count in a post-stratum if an adjustment is applied. This results when there is evidence of an overcount in the post-stratum.

"Smoothing" the Adjustment Factors

The next steps were "smoothing" the variances of these "raw" adjustment factors, "smoothing" the "raw" adjustment factors themselves to reduce sampling variance associated with them, and the production of final adjustment factors incorporating both smoothing steps. Because the PES was a sample, it was subject to sampling error. Sampling error is an estimate of the error associated with taking some of the population (a sample) rather than all of the population (a census). Disaggregating 377,000 PES persons to 1,392 post-strata produced some post-strata with small sample sizes, and therefore, high estimates of sampling error. The process of smoothing the "raw" adjustment factors to create final adjustment factors was a step to minimize the effect of sampling error.

Both "smoothing" steps were based on a multi-variate regression model. The factor smoothing step used observed characteristics that have been known to be correlated with undercount. A regression prediction model "predicted" the adjustment factor for each of the 1,392 post-strata. The final adjustment factor was then a weighted average of the originally observed adjustment factor (called "raw") and the modeled factor (from the regression prediction model.) For a post-stratum with low estimated sampling variance, there was heavy weight on the observed factor; and vice versa. The final adjustment factors by post-stratum are shown in attachment 3.

Small Area Estimation

The final adjustment factors were now ready to be used to produce adjusted counts for every block in the Nation. The PES can only produce "direct" estimates of the total population for relatively large geographic areas (i.e., the 1,392 post-strata). If there is a decision to adjust, however, the adjustment must be applied to each of the Nation's 4 million populated blocks. The Bureau developed a model that takes the adjustment factors produced for each of the 1,392 post-strata areas and uses them to estimate adjustment counts for each block. Since each of the post-strata crosses many blocks, the Bureau based its model on a critical assumption that coverage error is similar for all blocks that a post-stratum crosses.

Here are two examples of how block counts could be changed during this process. Suppose a census block with 200 people had 50 people who fell into a particular post-stratum. An adjustment factor of 1.05 was computed for that post-stratum, so 50 was multiplied 1.05, which comes to 52.5. Since procedures allowed adding only whole persons to a block, either 2 or 3 persons were added, based on a pre-specified procedure, to the persons in that post-stratum for that block. Other groupings of persons in the block in this example also were multiplied by the adjustment factor for the post-stratum into which they fell. Similarly, suppose there were 80 people in another post-stratum in a particular census block, and the adjustment factor was 0.94, indicating an overcount. 80 was multiplied by 0.94, which came to 75.2, so 4 or 5 person records were eliminated from that block.

The Bureau then produced a data file that included enumerated people plus people added (or subtracted) by adjustment. It did this by adding or subtracting "adjustment" persons with characteristics that were imputed from other persons in the same block. The "adjusted" data files could then be used to produce all required census tabulations.

The 1990 Post Enumeration Survey Evaluation Program

The Post Enumeration Survey (PES) was conducted to evaluate the coverage of the 1990 Decennial Census. Twenty evaluation projects were subsequently conducted to evaluate the PES.[2] This report briefly describes the objectives and implementation of these twenty PES evaluation projects.

[2] In this document, studies P-13 and P-14 are discussed as one study each, although each had two parts. Elsewhere, these parts may be discussed separately, which leads to a total of twenty-two studies.

Ten of the sources of potential error in the PES were addressed by the evaluation studies:

1. Missing Data.
2. Quality of the Reported Census Day Address.
3. Fabrication in the P-sample.
4. Matching Error.
5. Measurement of Erroneous Enumerations.
6. Balancing the Estimates of Gross Overcount and Gross Undercount.
7. Correlation Bias.
8. Small Area Estimation.
9. Late Census Data.
10. Total Error.

Each of these ten potential sources of error are herein described along with the specific PES Evaluation project used to evaluate or estimate that error.

More detailed project descriptions are found in the Project Plans dated July 31, 1990. For more detailed descriptions of the implementation and results of these projects, see the final reports of July, 1991, whose executive summaries can be found in Appendix 3.

1. Missing Data

Both the P- and E-samples contain missing data on enumeration status. The E-sample has cases where the information required to determine whether the person is correctly or erroneously enumerated in the census is not available. The P-sample has cases where the information needed to determine whether the person is enumerated in the census is not available.

Missing data occur in more than one way. The interviewer may be unable to obtain an interview during the P-sample interview or during the PES follow-up. A P- or E-sample questionnaire may not have all the demographic and housing information to establish correct enumeration status. Finally, even with all the information requested on the questionnaires, circumstances may be so unclear that the enumeration status cannot be resolved or determined.

Missing data on enumeration status were handled in the production PES in three ways: noninterviews to the P-sample interview were handled by a weight adjustment; missing demographic characteristics in the P- and E-samples (such as age or race) were imputed by means of a hot-deck procedure; and unresolved match status cases were handled by a logistic regression technique.

Missing data can affect the estimates of undercount in a number of ways. For example, if the number of imputed correct enumerations is too high, the undercount estimate will be biased upward, or if the number of imputed matches in the P-sample is too high, the undercount estimate is biased downward.

Project P1: Analysis of Reasonable Alternatives

The analysis was based on applying alternative missing data treatments, such as methods of handling proxy interviews and mover data, applying bootstrap samples and applying other logistic regression methodologies to study the sensitivity of the dual system estimate to the method of imputation of missing data. A narrow range of alternative estimates indicates robustness in the dual system estimates, indicating little uncertainty in the estimates due to missing data.

The following were the principal alternate imputation treatments:

P-sample Proxy Alternative: P-sample follow-up interviews marked as proxies (i.e. completed with nonhousehold member) were recoded to indicate that no interview was obtained during follow-up.

E-sample Proxy Alternative: E-sample follow-up interviews marked as proxies (i.e. completed with nonhousehold member) were recoded to indicate that no interview was obtained during follow-up.

P-sample Mover Alternative: Unresolved P-sample movers were imputed as if they were nonmovers.

1988 Style Logistic Regression Alternative: The 1990 production imputation model is quite different than the model that was used in the 1988 Dress Rehearsal. The 1988 Style Logistic Regression Model consists of several standard logistic regression models as in 1988.

Bootstrap Samples: Three E-sample and three P-sample bootstrap samples were drawn in order to measure the variation in the production dual system estimates given the PES sample of blocks. Each bootstrap consisted of selecting households with replacement within blocks.

Imputation Treatment Combinations: Dual system estimates were computed for imputation treatment combinations. The following treatment combinations were used:

P-sample Proxy and E-sample Proxy
P-sample Proxy and 1988 Style Model
E-sample Proxy and 1988 Style Model
P-sample Proxy, E-sample Proxy, and 1988 Style Model

Project P2: Distribution of Missing Data Rates

This study was based on analysis of the missing data rates observed for the P- and E- samples. The types of missing data of greatest interest are noninterviews for the initial PES interview, and unresolved cases which remain after the PES follow-up.

The objectives of PES evaluation project P2 are to determine the level and distribution of missing data by demographic and geographic breaks and to compare the distributions with the distribution of census undercount (overcount). Hence, the following estimates are examined for P2.

1. Outcome of Interview (PES, PES Follow-up, and PES Evaluations).
2. Proxy Rates (PES, PES Follow-up, and PES Evaluations).
3. Percentage of Item Imputation (Hot-Deck and Logistic Regression).
4. Correlation Between Item Imputation and Census Undercount.

Project P3: Evaluation of Imputation Methodology for Unresolved Match Status Cases

This study was based on a reinterview of a sample of the P- and E-sample cases that were unresolved after the completion of the PES production follow-up. The reinterview also included a sample of the initial PES incomplete interviews. The reinterview was conducted immediately following the final PES matching operation. The reinterview used a probing questionnaire and better quality interviewers. In addition, the reinterview procedure allowed greater opportunity to contact knowledgeable respondents.

The objectives of PES evaluation project P3 are to: (1) provide quantitative information on the effect of the match/enumeration status imputation procedures; (2) examine quantitative measures of the effect of the noninterview adjustment; and (3) examine the characteristics of the household noninterviews. Hence, the following aspects of the PES are evaluated in P3.

1. Match/Enumeration Status Imputation.
2. Converted PES Noninterview Households.
3. PES Noninterview Household Characteristics.

2. Quality of the Reported Census Day Address

Dual system estimation assumes that P-sample respondents can be linked, or matched, correctly to their census day address. This evaluation measures address reporting and the error in the number of people matching a census enumeration due to address reporting error. Census Day was on April 1, 1990. The PES was conducted in July and August, 1990. Thus, some of the

respondents had moved between the time the census was conducted and the PES was in the field. However, in spite of probes on the PES interview questionnaire, respondents may fail to report that they moved. This type of error may cause the matching operation to search the census in an area other than where the respondent was enumerated and to assign a nonmatch status to respondents who might have been enumerated.

Project P4: Quality of the Reported Census Day Address—Evaluation Follow-up

An additional reinterview of a sample of P-Sample cases from the production follow-up was conducted. The sample consisted of nonmatches and unresolved P-sample cases in the PES block clusters selected for the evaluation follow-up. Some matches from whole household matched households were subsampled within each cluster. In addition, matches were selected from partially matched households. A specially designed questionnaire with special probes was used by highly skilled enumerators (Census Bureau Field Representatives). The reinterview allowed greater opportunity to contact designated respondents and probe more deeply for census day accuracy of the PES process for identifying movers and the quality of mover address reporting. Therefore, reviewing these results allowed an assessment of the accuracy of the census day address reported in the production PES.

This evaluation is based on a follow-up and reinterview operation that took place immediately following the final PES matching operation. The follow-up operation consisted of a sample of P-sample matched and nonmatched persons who were excluded from the production follow-up. A review of the results of this follow-up addressed the questions concerning the assumptions underlying the rules that were used in determining which cases should be sent for the production follow-up. This operation was done after PES production matching had been concluded.

3. Fabrication in the P-Sample

Interviewers, for whatever reason, may fabricate persons within enumerated housing units. The PES program had an extensive quality control (QC) program that identified and corrected fabrications. However, even with the best of intentions fabrications potentially remain after this operation. Three studies were implemented to address the effect of any uncorrected fabrications that remained in the data set after the quality control operation. The first study (P5a) identifies the residual fabrication by means of the evaluation follow-up and revisit interviews; subsequent matching of these households will identify fabrications. The second study (P5) utilizes the PES field operation quality control records to estimate "upper bound" residual PES fabrications. The third study (P6) provides model-based estimates of fabrications by comparing, at the block level, interviewer nonmatch rates with "nearby" interviewer nonmatch rates. These comparisons provide an indication of the quality of the interviewers work.

Project P5a: Analysis of P-Sample Fabrication From Evaluation Follow-up Data

The evaluation follow-up described for Project P–4, provided estimates of P-sample fabricated persons. These estimated fabrications can be used as independent estimates (from the quality control) of the level of fabrications in the P-sample. In addition, the quality control operations for the PES interviewing were assessed by comparing the estimated residual error rate from quality control records with the estimated fabrication rate from the follow-up.

Project P5: Analysis of PES P-Sample Fabrications From PES Quality Control Data

The data for project P5 comes from the Quality Control operation of the PES interviewing phase. The purpose of the QC check is to confirm that the PES interviewer visited the correct housing unit and conducted the interview according to the survey procedures. The roster of names, ages and census day addresses are all verified during the interview for the QC sample. A P-sample questionnaire fails the QC check when the household roster is incorrect. When an error is detected, all the recent work of the production interviewer undergoes a QC reinterview. Fabricated households discovered as a result of the QC reinterview are not used and correct interviews are obtained. Overall, approximately 35 percent of the P-sample (i.e., 56,000 households) were reinterviewed in the QC operation of the PES interviewing phase through telephone calls and personal visits.

The central problem or assumption of investigation for project P5 is the estimation of the amount of residual (i.e., undetected) fabrication that exists in the P-sample after the QC operation has been concluded. This analysis provides estimates both in terms of households and persons within these households.

Project P6: Fabrication in the P-Sample: Interviewer Effect

The objective of P6 was to gain knowledge about possible undetected fabrication in the PES. Though it is expected that curbstoners make up only a fraction of the PES work force and the quality control detects and eliminates such curbstoning, the potential impact of undetected fabricated data can be serious. This type of error inflates the undercount estimate. In addition, the inflated nonmatch rates are likely differential, i.e., larger for some post-strata than others.

The purpose of this study was to evaluate the quality control procedure implemented in PES to see how effective it was in detecting fabrication. This was done by developing a model to predict the nonmatch rate from the actual nonmatch rate obtained by interviewers working in areas with households of similar demographic characteristics. The assumption underlying the model was the interviewers working in similar areas would have similar nonmatch rates and the deviations from the model would indicate undetected curbstoning. Standardized scores (Z-scores) were computed for each interviewer rather than comparing the absolute differences between the observed and the expected rates. This was done to take into account the size of an interviewer's assignment. Interviewers with large scores differed greatly from the model predication, and were identified as potential curbstoners or poor quality workers. These enumerators were further studied to determine where they had worked and whether they had been detected by the PES QC operation.

4. Matching Error

Errors can occur in the operation where P-sample persons are matched to the original census enumerations. This matching operation was conducted in seven processing offices (PO's). Even though great efforts were made to standardize this operation across all PO's, errors could be relatively concentrated. Two studies were conducted to examine this type of error. The first study (P7) utilized a team of professionals to dependently rematch a subsample of PES block clusters; this operation is referred to as the Matching Error Study. The rematchers had access to the match codes assigned by the PES production matchers, and worked on assignments in PO's other than their home PO where they worked on PES production. The rematch was designed

to estimate the net error rate in the assignment of enumeration status in the P-sample and the E-sample. The second study (P5) examined PES production quality control records. This analysis provides insight into the nature of PES production matching error by examining where differences occur within this multi-tiered operation.

Project P7: Estimates of Clerical Matching Error From the Evaluation

This evaluation was based on a rematch of a subsample of the PES blocks by highly skilled personnel. This project also allowed additional field work as required, when additional information was determined to be necessary to resolve specific cases. The assumption underlying the evaluation is that better training and personnel can detect systematic errors in the matching.

The subsample of blocks included in this evaluation was based on a stratified sample designed to give a higher probability of selection to blocks with potential matching problems. In addition, the highly skilled personnel used for this evaluation were assigned to work in different processing offices, to the extent possible, to minimize redoing blocks that they previously processed.

Project P8: Matching Error—Estimates of Clerical Matching Error in the P-Sample From Quality Assurance Results

This evaluation was carried out by comparing the results of the PES matching quality control operation to determine where potential inconsistencies existed.

At the conclusion of the computer matching, the clerical matching proceeds with an initial stage of clerical matching (CMG) followed by a more extensive stage of matching by another group of more qualified special matching group clerks (SMG1). Another special matching group (SMG2) also conducted matching on the same cases as the CMG and SMG1 stages. Discrepancies between the SMG1 and SMG2 are adjudicated by a higher level PES matching technician.

Comparing the differences between the various stages of matching can identify potential areas where matching error can exist. These findings may be of interest in interpreting the results of project P–7.

5. Measurement of Erroneous Enumerations

Some census enumerations are in fact erroneous. The following enumerations are erroneous:

(1) Duplicated persons.

(2) Fictitious persons.

(3) People who died before Census Day.

(4) People who were born after Census Day.

(5) People enumerated outside the search area where they were living on Census Day.

An estimate of erroneous enumerations is needed for the PES-census dual system estimate of the total population. Three studies investigate errors in classifying the enumeration status (correct or erroneous) of the E-sample persons. The first study (P10) utilized the same team of highly skilled professionals as did project P7 to dependently review the PES E-sample production results in a subsample of PES block clusters. This operation was part of the Matching Error Study. The focus was on the errors that occurred during PES production processing involving duplicates and fictitious persons; however, there was also an examination for the above (3), (4), and (5) type errors. The second study (P9a) utilized data collected from the evaluation follow-up interviews. The evaluation follow-up questionnaire was administered by more competent interviewers than was used by PES production. Also, this questionnaire had more probes than the standard PES production follow-up questionnaire. An alternative estimate of erroneous enumerations resulted from this operation. The third study (P9) is a consistency check; an examination of PES E-sample cross-tabulations provides evidence as to whether a particular type of error in classifying enumeration status is present in the data.

Project P10: Accurate Measurement of Census Erroneous Enumerations—Clerical Error in Assignment of Census Enumeration Status

This evaluation was conducted as part of the rematch work described for Project P7, Evaluation of Clerical Error in the P-sample matching. The study used the same subsample of PES blocks. The E-sample for these blocks underwent the intensive review by highly skilled matchers. This work was supplemented by the reinterview described for Project P9a. The objective was to determine whether the production matching operations are correctly classifying census erroneous enumerations.

The combination of both of these projects—P7 and P10- is referred to as the Matching Error Study (MES).

Project P9a: Accurate Measurement of Census Erroneous Enumerations—Evaluation Follow-up

A sample of E-sample cases was sent for a PES evaluation field follow-up to determine whether a person was correctly enumerated in the Census. The sample included both E-sample cases where an interview was obtained and those where a follow-up interview was not completed. The follow-up reinterview was conducted with more experienced enumerators using a more probing questionnaire. In addition, the follow-up allows greater opportunity to contact a respondent and obtain a complete interview. This same evaluation follow-up was used as part of Project P7 and Project P4. The completed evaluation follow-up interview was clerically matched back to the census to assess the accuracy of the PES production procedure in classifying a persons enumeration status.

Project P9: Accurate Measurement of Census Erroneous Enumeration—Consistency Checks

This evaluation was based on examining a variety of cross tabulations prepared from the PES E-sample for each evaluation stratum. Data such as the following was cross-tabulated:

(1) Enumeration status (correct enumeration, erroneous enumeration).

(2) Type of respondent (original census residents, current residents, neighbors, other proxies).

(3) Source of census enumeration (mailback, enumerator return).

(4) Age group.

(5) Enumeration status of other household members (whole household erroneously enumerated, partial household erroneously enumerated).

The cross tabulations were examined to assess whether the pattern of erroneous enumerations was consistent with previous experience and research findings. Unexplainable discrepancies in the erroneous enumerations were considered as potential indications that the PES process incorrectly measured erroneous enumerations.

6. Balancing the Estimates of Gross Overcount and Gross Undercount

Because of the limited search area that is used to estimate P-sample nonmatches and E-sample erroneous enumerations, balancing error can occur. There was no plan to obtain a direct estimate of this type of error. The components of balancing error are included in the measures of errors that are produced from other studies such as P–7 and P–10 (matching error studies)

Project 11: Balancing Error Evaluation—Percentage of Matches Found Outside Sample Blocks

This evaluation used supplementary information to assess whether balancing is an issue in the performance of PES. Inconsistencies found are indications of potential failure of balancing and should be indications of which of the evaluation studies should reflect these errors. The P-sample match rates for the PES blocks and surrounding blocks were compared with the rates at which E-sample persons are found to be in the PES blocks and in the surrounding blocks. These rates should be the about the same. Differences found were evaluated using the results of the evaluation follow-up.

The rate at which movers matched in the blocks to which they were geocoded was also studied. These rates should be consistent with the corresponding rates for the P-sample nonmovers in the same post-strata.

7. Correlation Bias

The dual system estimation used for the PES is based on several independence assumptions. Two that are of particular interest are homogeneity and causality. The homogeneity assumption requires that everyone has the same probability of inclusion in both the P-sample and the census within the same post-stratum. Failure of the homogeneity assumption usually is seen in an understatement of the undercount for a population group (such as Black males). The causality assumption requires that inclusion in the census does not influence inclusion in the P-sample or vice versa.

Two studies were directed at studying the adequacy of the homogeneity assumption. The first study (P13) compares the dual system estimates with demographic analysis to obtain an estimate of correlation bias at the national level. The second study (P17) is qualitative in nature, and compares the PES dual system estimates, the individual P- and E-samples, and demographic analysis to determine if inconsistencies exist that could indicate the presence of correlation bias due to failure of the homogeneity assumption.

The causality assumption is investigated by two qualitative studies (P14 a and b). The first of these studies pairs non-PES blocks with similar PES blocks and compares characteristics. There should be no difference between these blocks except for the random variation introduced by sampling. The second study uses a debriefing of field interviewers to assess the potential for correlation bias.

Project P13: Use of Alternative Dual System Estimators to Measure Correlation Bias

Alternative dual system estimators were developed using information from demographic analysis to try to address the problem of correlation bias due to failure of the homogeneity assumption—when people missed by the census are more likely to be missed by the PES than those included in the census and vice-versa. This was done by using demographic analysis sex ratios (the ratio of males to females) and the PES dual system estimates for females to create an alternative estimate for males. The DSE for females was multiplied by the sex ratio appropriate for each PES age group. By comparing these alternative estimates for males with the PES dual system estimates for males gives an estimate of correlation bias at the national level. The estimated correlation bias was then allocated to the individual PES male post-strata proportional to P-sample non-matches. This permitted estimates of correlation bias to be produced at the individual post-stratum level.

Project P17 Internal Consistency of Estimates

This study has two objectives: (1) to evaluate the reasonableness of the age sex distribution in the census and PES estimates and (2) to compare the PES and demographic analysis (DA) estimates of undercount to make some assessment of the accuracy of the PES estimates. For these purposes, sex ratios and information on undercount rates from the PES and DA were used. Sex ratio are used to evaluate if overall results on sex distribution are reasonable. Because demographic analysis estimates are available at the national level only, most comparison are limited to analyzing data for the U.S. by race black and non-black.

Project P14 Independence of the Census and P-Sample, Comparison of Blocks

The analysis for this project is directed at assessing the existence of correlation bias due to failure of the causality assumption:

The probability of an individual being included in the P-sample is not altered by inclusion in the census, and the probability of being included in the census is not altered by inclusion in the P-sample.

Several steps were implemented to study the existence of correlation bias. First, a sample of PES blocks paired with comparable non-PES blocks was drawn. The sample was selected by type of enumeration area (TEA) in order to do analyses isolating these groups. Each type of enumeration was analyzed as a separate data set since the timing of the PES and census operations were different across areas. Therefore, any PES effects on the census would be different for each TEA and should be tested using separate data sets.

The difference from PES blocks and non-PES blocks were the focus of the tests. For each block, relevant data were extracted from the final census files in January, 1991 and aggregated from person records to block level records. The preliminary variables were organized a priori into groups: block size, population coverage, housing unit status, mailback, field response, and edit & quality. The data were tested for relevance, completeness, and redundancy.

8. Small Area Estimation

Project P12: Evaluation of the Synthetic Assumption

Synthetic adjustment is used in the PES to "carry down" the estimated adjustment factors to the census counts in each post stratum. This synthetic adjustment assumes that the probability of being missed by the census is constant for each person within the post-stratum.

The coverage error may vary substantially within the PES strata although the post strata were drawn so as to be homogeneous with respect to expected coverage error. The goal of this study is to verify that the assumption underlying the synthetic adjustment is valid.

The analysis was based on studying the homogeneity of several different block level statistics. Three different types of analysis were conducted. First the distributions of census characteristics thought to be highly correlated with coverage error (e.g., mail return rate) were examined. Secondly, the distribution of the components of coverage error at the block level were studied. These components were erroneous enumeration rates and P-sample nonmatch rates. Finally, the production smoothing model was used to predict a block level adjustment factor for the same sample of blocks used for the first analysis.

The analysis concentrated on determining whether the block level statistics clustered unusually by state within the PES post-strata. Further analysis to examine clustering at other levels such as place and county remains to be carried out.

9. Late Late Census Data

Project P18: Evaluation of Late Late Census Data

Census data capture was completed after the completion of the last planned PES matching operation which was Late Census Data matching. A small amount of changes to census data (census additions, deletions and updated person data) resulted from the late census data capture activities. A portion of these changes were included into the PES results through the Late Late Census Data (LLCD) matching operation. The remainder of these late census data changes were not processed due to time constraints, and were not included in the PES results. The Evaluation of Late Late Census Data (Project 18) examines the effect that the late census data changes not included in the PES have on the PES estimates of undercount. The remaining late-late census data were processed to determine the effect that this would have had on the dual system estimates.

10. Total Error

Project 16: Total Error in PES Estimates for Evaluation Post Strata

The dual system estimator used in the estimation for the PES is known to be subject to various components of nonsampling error, in addition to sampling error. The PES evaluation program includes studies that provide direct measures of error due to nonsampling and sampling error components. These errors combine in the dual system estimator model to cause differences from population counts that would be attained under an error-free program. The difference between the PES estimate and the error-free count is referred to as the total error.

Project P16 evaluates both the components of error and the total error in the PES estimates for the 13 evaluation post strata. The components of error are response correlation bias (also called model bias), matching error, quality of reported Census Day address, fabrication in the P-sample, processing error in the E-sample, data collection error in the E-sample, error in balancing the estimates of the gross overcount and the gross undercount missing data (imputation error), sampling variance, and ratio estimator bias.

The evaluation of the total error assesses the overall accuracy of the PES estimates of population size and the census undercount rate. A synthesis of the components errors provides estimates of the bias and variance. This analysis then assesses the combined effect of the errors on the PES estimate of the undercount rate. The estimates of the mean and variance of the distributions of the component errors are based on the conclusions drawn from the various evaluation studies. The simulation method produced an estimate of the bias and variance of the estimated undercount rate.

The results of the total error model were also used in a loss function analysis to assess the accuracy of the distributions of population across states, places, and counties for the adjusted and unadjusted census. This analysis was carried out by forming target populations from the results of the total error work. The biases measured by the PES evaluations were incorporated into PES dual system estimates to produce corrected estimates of the population. These corrected estimates were designated as the target populations. The adjusted and unadjusted census population distributions were compared to the target population distributions using several loss functions. The comparisons were conducted at the state level and at the place and county level for the following size categories:

Places under 25,000 population.
Places of between 25,000 and 50,000 population.
Places of size over 50,000.
Counties under 200,000.
Counties larger than 200,000.

In addition, results were also produced for places and counties over 100,000 population.

Demographic Analysis

The Census Bureau's companion coverage measurement program to the PES was demographic analysis. The demographic coverage estimates could only be used to evaluate the completeness of coverage of the 1990 census at a national level and only for race (Black/Non-Black), sex, and age groups. Demographic analysis could not provide even reasonably reliable coverage estimates for the Hispanic, Asian/Pacific Islander, or American Indian/Native Alaskan populations because these characteristics have not always been recorded on birth and death certificates; nor can the demographic method provide direct estimates of the resident population at the State or substate level. However, the PES measured under or overcounts of these groups. The demographic coverage estimates were compared to the post-enumeration survey coverage estimates to assess the overall consistency of the two sets of estimates at the national level.

Demographic analysis uses historical data on births, deaths, and legal immigration; estimates of emigration and undocumented immigration; and Medicare data to develop an independent estimate of the resident population on census day. The estimate is compared with the census count to yield a measure of net census coverage and net undercount. The particular procedure that is used to estimate coverage nationally in 1990 for the various demographic subgroups depends primarily on the nature and availability of the required demographic data. Birth and death records are available for the entire United States from 1933 on for developing estimates of population at ages under 57 in 1990. In estimating births for each year, the Bureau added to the number of registered births an estimate of underregistration. Underregistration was estimated based on tests conducted in 1940, 1950, and 1964–1968. If the estimates of underregistration are off, they could have a significant effect on undercount estimates because birth data are by far the largest component in estimating the population through demographic analysis. In fact, in producing the demographic estimates of population for 1990 the Bureau revised the estimates for certain Black birth cohorts to account for biases that recent research identified in the birth registration test result of 1940.

National birth and death records are not available before 1933, so the Bureau had to find other ways to estimate the population size of these cohorts in 1990 (ages 55 and over were estimated). For the population 65 and over, administrative data on aggregate Medicare enrollments for 1990 (adjusted for underenrollment) are used to estimate population and net coverage. For the Non-black population aged 55 to 64 in 1990, the estimates of population are based primarily on national birth estimates for 1925–1934 developed by Whelpton. For the Black population aged 55 to 64 in 1990, the estimates of population are based on revisions of estimates for the cohort in 1960 developed by Coale and Rives.

In addition to subtracting deaths, the estimates of births described above are augmented to account for change due to immigration, emigration, and net international movement abroad of citizens (including the Armed Forces and Puerto Rican migrants). The various components of net migration vary significantly in their completeness and quality. The United States does not keep emigration records. Therefore, an estimate had to be made of those who have left the country. While the United States does have good records of legal

immigration, there is no accurate estimate of illegal immigration—the most elusive demographic component of population change. The Census Bureau has developed a preliminary estimate for undocumented residents in 1990 based on analysis of survey data and administrative records of the Immigration and Naturalization Service (INS). The INS now collects different information than it did prior to 1980. Recent immigration reform further complicated the effort to estimate legal immigration and undocumented residents. Although the legislative reform allowed many undocumented aliens to receive amnesty, some of these persons may not actually reside in the United States.

It should be noted that before the demographic estimates of population for race groups are compared to the census to calculate the net undercount, the race categories of the census counts must be "modified" so that they are consistent with the race categories of the historical demographic estimates. Specifically, 9.8 million persons in the 1990 census (mostly of Hispanic origin) reported their race in the "Other race-not specified" category, a category not included in the demographic estimates. This modification added 497,000 persons to the census count for Blacks. Also, the age categories of the 1990 census counts have been "modified" so they are consistent with the April 1, 1990 time reference of the demographic estimates.

It is important to emphasize that results of demographic analysis are not exact but are estimates. To a large extent, they were based on assumptions and best professional judgment. As in the PES, the Bureau tried to estimate potential error in the data produced by demographic analysis. To estimate that overall error, the Bureau conducted 11 detailed demographic analysis evaluation studies to find out as much as possible about each possible source of error—the specific projects are identified in Table 1. Based on these studies, the Bureau developed a range of error around the demographic analysis estimates. Since these evaluation projects and the demographic error model represent an evaluation program new for the 1990 census, the assessments of potential error are subject to change and improvement over time just as the basic demographic estimates of coverage have been.

Table 1.— The Eleven Demographic Analysis Evaluation Projects

D1..... Error in Birth Underregistration Completeness Estimates.

Table 1.— The Eleven Demographic Analysis Evaluation Projects—Continued

D2..... Uncertainty in Estimates of Undocumented Aliens.
D3..... Uncertainty in Estimated White Births, 1915–1935.
D4..... Uncertainty in Estimated Black Births, 1915–1935.
D5..... Robustness of Estimated Number of Emigrants.
D6..... Robustness of Estimates of the Population 65 and Older.
D7..... Uncertainty Measures for Other Components.
D8..... Uncertainty of Models to Translate 1990 Census Concepts into Historical Racial Classifications.
D9..... Inconsistencies in Race Classifications of the Demographic Estimates and the Census.
D10..... Differences Between Preliminary and Final Demographic Estimates.
D11..... Total Error in the Demographic Estimates.

Attachment 1

PES SAMPLE SIZE BY STATE (P-SAMPLE)

State names	Blocks	Clusters	Housing units
Alabama	280	168	4,706
Alaska	27	16	946
Arizona	569	115	5,046
Arkansas	161	77	2,230
California	652	390	13,013
Colorado	401	101	3,290
Connecticut	74	55	1,816
Delaware	19	12	460
District of Columbia	22	18	657
Florida	298	198	5,973
Georgia	189	112	3,320
Hawaii	49	19	599
Idaho	226	51	1,697
Illinois	300	221	7,553
Indiana	149	92	2,540
Iowa	179	86	2,491
Kansas	264	74	2,188
Kentucky	177	107	3,116
Louisiana	165	105	3,481
Maine	216	67	2,292
Maryland	72	56	2,162
Massachusetts	162	107	3,185
Michigan	232	152	4,959
Minnesota	256	99	3,186
Mississippi	179	103	2,696
Missouri	215	116	3,369
Montana	409	46	1,755
Nebraska	140	44	1,257
Nevada	66	27	1,195
New Hampshire	118	49	1,987
New Jersey	117	91	2,752
New Mexico	553	68	2,533
New York	520	371	12,210
North Carolina	209	126	3,754
North Dakota	205	19	679
Ohio	216	146	4,491
Oklahoma	271	93	2,737
Oregon	310	83	2,575
Pennsylvania	499	303	9,517
Rhode Island	32	24	832
South Carolina	107	58	1,900
South Dakota	230	18	686

PES SAMPLE SIZE BY STATE (P-SAMPLE)—Continued

State names	Blocks	Clusters	Housing units
Tennessee	243	173	4,858
Texas	845	436	12,807
Utah	212	40	1,351
Vermont	115	28	1,423
Virginia	144	87	2,609
Washington	352	111	3,939
West Virginia	49	31	911
Wisconsin	141	76	2,264
Wyoming	488	26	801
National Total	12,124	5,290	168,794

Attachment 2

1990 Post-Enumeration Survey Post Strata

The 1990 Post-Enumeration Survey (PES) will provide direct estimates for 1392 post strata. The post strata are designed to divide the PES sample blocks into groups which have similar characteristics. This helps the Census Bureau to estimate the coverage of the 1990 decennial census more accurately.

The post strata are defined by census division, area (city, non-city, rural, etc.), race, Hispanic origin, tenure group, sex, and age. Tenure refers to whether housing units are owned or rented. Each post strata is given an eight digit code. The attached document shows 116 post strata and the corresponding first six digits of the post stratum code for each. The last two digits are not delineated on the attachment. They define sex and age group. There are six age group classifications. What follows is an explanation of the post strata coding system:

The first digit of each given eight digit code defines the census division. The nine census divisions and the states in each census division are:

1—New England—Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, and Vermont
2—Middle Atlantic—New Jersey, New York, and Pennsylvania
3—South Atlantic—Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, and West Virginia
4—East South Central—Alabama, Kentucky, Mississippi, Tennessee
5—West South Central—Arkansas, Louisiana, Oklahoma, and Texas
6—East North Central—Illinois, Indiana, Michigan, Ohio, and Wisconsin
7—West North Central—Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota
8—Mountain—Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming

9— Pacific—Alaska, California, Hawaii, Oregon, and Washington

Within each census division, the geographic areas are divided by type of area. There are nine possible type of area codes:

0—Central cities in explicitly named PMSAs (see description below)
1—Central cities in large metropolitan areas (Type I MAs)
2—Central cities in small metropolitan areas (Type II MAs)
3—Central cities in a metropolitan area regardless of size
4—Non-central city areas in the New York PMSA
5—Non-central city areas in large metropolitan areas (Type I MAs)
6—Non-central city areas in small metropolitan areas (Type II MAs)
7—Non-central city areas in metropolitan areas
8—Non-metropolitan areas incorporated places with 10,000 + population
9—Balance of non-metropolitan areas

A PMSA is a Primary Metropolitan Statistical Area. There are four explicitly named PMSAs in the 1990 PES post strata. These PMSAs and the census division in which they are located are:

- The New York City PMSA in the Middle Atlantic division,
- The Houston PMSA plus the Dallas PMSA, plus the Fort Worth PMSA in the West South Central division,
- The Chicago PMSA plus the Detroit PMSA in the East North Central division,
- The Los Angeles-Long Beach PMSA in the Pacific division.

A large metropolitan area (type I MA) is an area whose largest central city has a population of at least 250,000 using the 1990 census person count.

A small metropolitan area (type II MA) is an area which does not have any central cities with a population of 250,000 or more.

The balance of non-metropolitan areas consist of areas which are not included in area type number 8. This would consist primarily of rural areas.

Any post strata can include up to three area types. The area types included in a stratum are delineated in the second to fourth digits of the post strata code. For instance, post strata code 578910 includes area types 7, 8, and 9. But most post strata contain only one area type. If a post stratum has only one area type, the second digit of the post stratum code indicates the area type, and the third and fourth digits are zero. In general, each of the second through fourth digits is filled with a zero from the right if a given geographic area of post stratum contains less than three area types.

The race/hispanic origin is determined by the fifth digit of the post stratum code. The tenure group is determined by the sixth digit of the post stratum code. These three attributes are combined in the coding system. The possible race/hispanic origin groups are: Black, Non-Black Hispanic, Asian-Pacific Islander, American Indian, and Other. A post stratum can consist of more than one race/hispanic origin group. This is reflected in the definitions below. The tenure designation defines whether the persons in the geographic area are owners or renters. Some geographic areas were not divided by tenure. The possible codes for the fifth and sixth digits are:

10—Black (Renter & Owner)
11—Black Renter
12—Black Owner
20—Non-Black Hispanic (Renter & Owner)
21—Non-Black Hispanic Renter
22—Non-Black Hispanic Owner
30—All Other (Renter & Owner)
31—All Other Renter
32—All Other Owner
40—Asian-Pacific Islander (Renter & Owner)
41—Asian-Pacific Islander Renter
42—Asian-Pacific Islander Owner
50—Black and Non-Black Hispanic (Renter & Owner) & Non-Black Non-Asian-Pacific Islander Hispanic
60—American Indian

The seventh digit of the post stratum code defines the sex.

1—Male
2—Female

Within sex there are six age groups, the eighth digit. The age groups are:

1—0–9
2—10–19
3—20–29
4—30–44
5—45–64
6—65+

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]

Stratum code	Factor
09006011	1.166
09006012	1.182
09006013	1.158
09006014	1.197
09006015	1.117
09006016	1.143
09006021	1.130
09006022	1.169
09006023	1.166
09006024	1.071
09006025	1.068
09006026	1.097
13003011	1.001
13003012	0.987
13003013	1.034
13003014	0.984
13003015	0.991
13003016	0.964
13003021	0.989
13003022	0.979
13003023	1.007
13003024	0.976
13003025	0.981

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
13003026	0.957
13705011	1.068
13705012	1.027
13705013	1.079
13705014	1.068
13705015	1.040
13705016	1.012
13705021	1.047
13705022	1.008
13705023	1.050
13705024	1.041
13705025	1.012
13705026	1.015
17003011	1.020
17003012	0.989
17003013	1.030
17003014	0.990
17003015	1.014
17003016	0.987
17003021	1.016
17003022	0.974
17003023	1.021
17003024	1.007
17003025	0.994
17003026	0.975
18003011	1.025
18003012	0.980
18003013	1.030
18003014	1.028
18003015	1.011
18003016	0.984
18003021	1.007
18003022	0.974
18003023	1.003
18003024	1.008
18003025	1.002
18003026	0.995
19003011	1.022
19003012	1.008
19003013	1.073
19003014	1.028
19003015	1.024
19003016	1.013
19003021	1.017
19003022	1.003
19003023	1.018
19003024	1.013
19003025	0.996
19003026	1.006
20001111	1.111
20001112	1.076
20001113	1.122
20001114	1.102
20001115	1.043
20001116	1.077
20001121	1.112
20001122	1.031
20001123	1.090
20001124	1.114
20001125	1.038
20001126	1.050
20001211	1.022
20001212	0.994
20001213	1.010
20001214	0.990
20001215	0.991
20001216	0.980
20001221	1.055
20001222	0.997
20001223	1.019
20001224	0.989
20001225	0.982
20001226	0.981
20002011	1.050
20002012	0.990
20002013	1.053
20002014	1.018
20002015	1.024

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
20002016	1.002
20002021	0.995
20002022	1.002
20002023	1.033
20002024	1.015
20002025	1.005
20002026	0.994
20003111	0.993
20003112	0.997
20003113	1.113
20003114	1.041
20003115	1.016
20003116	0.964
20003121	1.001
20003122	0.954
20003123	1.054
20003124	1.011
20003125	0.987
20003126	0.935
20003211	0.988
20003212	0.993
20003213	1.013
20003214	1.001
20003215	1.017
20003216	0.954
20003221	1.030
20003222	0.980
20003223	1.017
20003224	1.012
20003225	0.972
20003226	1.002
20004011	1.130
20004012	1.124
20004013	1.156
20004014	1.107
20004015	1.104
20004016	1.095
20004021	1.128
20004022	1.069
20004023	1.130
20004024	1.133
20004025	1.101
20004026	1.081
21001111	1.092
21001112	1.037
21001113	1.126
21001114	1.107
21001115	1.063
21001116	1.033
21001121	1.090
21001122	1.076
21001123	1.127
21001124	1.083
21001125	1.055
21001126	1.035
21001211	1.022
21001212	1.040
21001213	1.029
21001214	0.989
21001215	0.992
21001216	0.988
21001221	1.037
21001222	0.984
21001223	1.010
21001224	0.969
21001225	0.986
21001226	0.989
21003111	1.002
21003112	0.970
21003113	1.034
21003114	1.003
21003115	0.969
21003116	0.984
21003121	0.991
21003122	0.997
21003123	1.001
21003124	1.008
21003125	0.985

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
21003126	0.959
21003211	1.024
21003212	0.956
21003213	1.013
21003214	1.020
21003215	0.998
21003216	0.982
21003221	1.005
21003222	0.995
21003223	1.049
21003224	0.987
21003225	0.991
21003226	0.979
22001011	1.127
22001012	1.031
22001013	1.129
22001014	1.142
22001015	1.103
22001016	0.057
22001021	1.157
22001022	1.080
22001023	1.140
22001024	1.071
22001025	1.074
22001026	1.058
22003011	0.991
22003012	0.989
22003013	1.037
22003014	1.022
22003015	1.017
22003016	0.975
22003021	1.008
22003022	0.968
22003023	1.002
22003024	0.993
22003025	1.009
22003026	0.974
23002011	1.010
23002012	1.021
23002013	1.071
23002014	1.022
23002015	1.008
23002016	0.972
23002021	1.024
23002022	0.976
23002023	1.008
23002024	1.055
23002025	1.010
23002026	0.995
24003011	1.053
24003012	0.991
24003013	1.020
24003014	1.012
24003015	0.996
24003016	0.981
24003021	1.017
24003022	1.006
24003023	1.057
24003024	0.991
24003025	0.979
24003026	0.978
24505011	1.071
24505012	1.057
24505013	1.115
24505014	1.095
24505015	1.060
24505016	1.060
24505021	1.108
24505022	1.032
24505023	1.063
24505024	1.085
24505025	1.057
24505026	1.014
25003011	1.009
25003012	0.983
25003013	1.037
25003014	1.031
25003015	0.981

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
25003016	0.971
25003021	1.029
25003022	1.018
25003023	1.033
25003024	1.002
25003025	0.983
25003026	0.973
26003011	1.018
26003012	0.990
26003013	1.040
26003014	0.994
26003015	0.991
26003016	0.984
26003021	1.003
26003022	0.978
26003023	0.999
26003024	1.011
26003025	0.994
26003026	0.984
28003011	1.015
28003012	0.967
28003013	1.017
28003014	1.030
28003015	1.006
28003016	0.991
28003021	1.061
28003022	0.975
28003023	1.016
28003024	0.998
28003025	0.992
28003026	0.984
29003011	1.014
29003012	0.991
29003013	1.042
29003014	1.019
29003015	0.993
29003016	1.001
29003021	1.009
29003022	0.999
29003023	1.041
29003024	1.017
29003025	0.982
29003026	0.986
29995011	1.071
29995012	1.048
29995013	1.067
29995014	1.074
29995015	1.037
29995016	1.033
29995021	1.055
29995022	1.045
29995023	1.054
29995024	1.068
29995025	1.054
29995026	1.039
31001111	1.133
31001112	1.102
31001113	1.106
31001114	1.131
31001115	1.076
31001116	1.086
31001121	1.155
31001122	1.096
31001123	1.105
31001124	1.069
31001125	1.067
31001126	1.037
31001211	1.066
31001212	1.017
31001213	1.030
31001214	1.024
31001215	0.990
31001216	0.991
31001221	1.037
31001222	1.008
31001223	1.027
31001224	0.992
31001225	0.994

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
31001226	0.977
31003111	1.085
31003112	1.038
31003113	1.073
31003114	1.065
31003115	1.047
31003116	0.993
31003121	1.054
31003122	1.055
31003123	1.099
31003124	1.013
31003125	1.011
31003126	0.983
31003211	1.039
31003212	1.035
31003213	1.048
31003214	1.035
31003215	0.983
31003216	0.985
31003221	1.035
31003222	1.031
31003223	1.073
31003224	1.021
31003225	0.979
31003226	1.008
32001011	1.052
32001012	1.035
32001013	1.072
32001014	1.037
32001015	1.015
32001016	1.006
32001021	1.084
32001022	1.028
32001023	1.083
32001024	1.047
32001025	1.003
32001026	0.981
32003011	1.065
32003012	1.066
32003013	1.080
32003014	1.046
32003015	1.027
32003016	0.986
32003021	1.048
32003022	1.032
32003023	1.039
32003024	1.007
32003025	0.987
32003026	0.998
33002011	1.106
33002012	1.064
33002013	1.101
33002014	1.088
33002015	1.005
33002016	0.985
33002021	1.101
33002022	1.056
33002023	1.091
33002024	1.065
33002025	0.984
33002026	0.984
35001011	1.042
35001012	1.012
35001013	1.034
35001014	1.007
35001015	0.996
35001016	0.990
35001021	1.040
35001022	1.012
35001023	1.045
35001024	1.017
35001025	1.007
35001026	0.986
35003011	1.030
35003012	0.997
35003013	1.032
35003014	1.008
35003015	0.982

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
35003016	0.985
35003021	1.036
35003022	1.015
35003023	1.035
35003024	0.995
35003025	0.975
35003026	0.983
36001011	1.074
36001012	1.033
36001013	1.034
36001014	1.044
36001015	1.018
36001016	1.003
36001021	1.035
36001022	1.043
36001023	1.051
36001024	1.042
36001025	1.010
36001026	1.001
36003011	1.052
36003012	1.007
36003013	1.039
36003014	1.042
36003015	0.991
36003016	0.992
36003021	1.069
36003022	1.062
36003023	1.038
36003024	1.043
36003025	1.028
36003026	0.994
37892011	1.030
37892012	1.083
37892013	1.133
37892014	1.074
37892015	1.007
37892016	1.017
37892021	1.090
37892022	1.021
37892023	1.068
37892024	1.059
37892025	0.994
37892026	0.971
38001011	1.025
38001012	1.001
38001013	1.023
38001014	1.033
38001015	1.023
38001016	0.984
38001021	1.057
38001022	1.015
38001023	1.048
38001024	1.021
38001025	0.953
38001026	0.963
38003011	1.058
38003012	1.015
38003013	1.066
38003014	1.020
38003015	1.000
38003016	0.981
38003021	1.046
38003022	1.010
38003023	1.026
38003024	1.007
38003025	0.995
38003026	0.979
39001011	1.057
39001012	1.039
39001013	1.021
39001014	1.039
39001015	1.023
39001016	0.981
39001021	1.071
39001022	1.045
39001023	1.045
39001024	0.999
39001025	0.994

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
39001026	0.979
39003011	1.047
39003012	1.014
39003013	1.063
39003014	1.035
39003015	1.002
39003016	0.994
39003021	1.058
39003022	1.045
39003023	1.060
39003024	1.022
39003025	1.022
39003026	0.997
41003111	1.084
41003112	1.074
41003113	1.056
41003114	1.078
41003115	1.015
41003116	0.989
41003121	1.075
41003122	1.050
41003123	1.042
41003124	1.062
41003125	1.025
41003126	0.982
41003211	1.045
41003212	1.032
41003213	1.042
41003214	1.043
41003215	1.011
41003216	0.994
41003221	1.065
41003222	1.028
41003223	1.064
41003224	1.038
41003225	1.006
41003226	1.001
42003011	1.075
42003012	1.018
42003013	1.072
42003014	1.042
42003015	1.002
42003016	0.996
42003021	1.036
42003022	1.055
42003023	1.058
42003024	1.020
42003025	0.987
42003026	0.975
43005011	1.093
43005012	1.075
43005013	1.090
43005014	1.085
43005015	1.055
43005016	1.009
43005021	1.116
43005022	1.041
43005023	1.083
43005024	1.043
43005025	1.003
43005026	0.987
47003011	1.041
47003012	1.023
47003013	1.043
47003014	1.042
47003015	1.002
47003016	0.987
47003021	1.051
47003022	1.024
47003023	1.050
47003024	1.015
47003025	1.007
47003026	0.990
47895011	1.062
47895012	1.008
47895013	1.020
47895014	1.042
47895015	1.004

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
47895016	0.999
47895021	1.050
47895022	1.011
47895023	1.038
47895024	1.027
47895025	1.004
47895026	0.975
48003011	1.039
48003012	1.029
48003013	1.053
48003014	1.020
48003015	1.003
48003016	0.996
48003021	1.048
48003022	1.017
48003023	1.032
48003024	1.014
48003025	0.988
48003026	1.004
49003011	1.032
49003012	1.021
49003013	1.066
49003014	1.012
49003015	0.990
49003016	0.998
49003021	1.032
49003022	1.016
49003023	1.060
49003024	1.010
49003025	0.987
49003026	1.010
50001011	1.098
50001012	1.081
50001013	1.096
50001014	1.072
50001015	1.042
50001016	1.020
50001021	1.104
50001022	1.057
50001023	1.117
50001024	1.058
50001025	1.022
50001026	0.995
50002011	1.088
50002012	1.044
50002013	1.143
50002014	1.063
50002015	1.014
50002016	0.963
50002021	1.128
50002022	1.079
50002023	1.105
50002024	1.043
50002025	0.992
50002026	0.958
50003111	1.058
50003112	1.050
50003113	1.073
50003114	1.060
50003115	1.035
50003116	1.008
50003121	1.080
50003122	1.043
50003123	1.053
50003124	1.019
50003125	1.028
50003126	0.990
50003211	1.033
50003212	1.004
50003213	1.054
50003214	1.020
50003215	1.017
50003216	0.977
50003221	1.033
50003222	1.019
50003223	1.027
50003224	1.025
50003225	0.997
50003226	0.999
51003111	1.041
51003112	1.038
51003113	1.027
51003114	1.032
51003115	1.014
51003116	0.982
51003121	1.059
51003122	1.039
51003123	1.069
51003124	1.028
51003125	0.999
51003126	0.980
51003211	1.032
51003212	1.014
51003213	1.039
51003214	1.012
51003215	0.994
51003216	0.984
51003221	1.027
51003222	1.011
51003223	1.041
51003224	1.005
51003225	0.994
51003226	0.985
52003011	1.053
52003012	1.034
52003013	1.056
52003014	1.038
52003015	1.003
52003016	0.995
52003021	1.045
52003022	1.017
52003023	1.053
52003024	1.027
52003025	0.994
52003026	0.988
53001011	1.079
53001012	1.034
53001013	1.099
53001014	1.057
53001015	1.032
53001016	1.001
53001021	1.089
53001022	1.047
53001023	1.074
53001024	1.045
53001025	0.989
53001026	0.997
53002011	1.065
53002012	1.037
53002013	1.051
53002014	1.033
53002015	0.974
53002016	0.970
53002021	1.095
53002022	1.023
53002023	1.094
53002024	1.048
53002025	0.971
53002026	0.979
57003011	1.044
57003012	1.043
57003013	1.050
57003014	1.024
57003015	0.999
57003016	0.989
57003021	1.033
57003022	1.032
57003023	1.048
57003024	1.030
57003025	0.993
57003026	0.971
57891011	1.069
57891012	1.016
57891013	1.041
57891014	1.033
57891015	1.004
57891016	0.988
57891021	1.032
57891022	1.003
57891023	1.060
57891024	1.013
57891025	0.992
57891026	0.985
57892011	1.056
57892012	1.058
57892013	1.077
57892014	1.065
57892015	1.047
57892016	1.002
57892021	1.081
57892022	1.047
57892023	1.059
57892024	1.043
57892025	1.011
57892026	1.015
58003011	1.027
58003012	0.994
58003013	1.048
58003014	1.030
58003015	0.999
58003016	0.978
58003021	1.027
58003022	1.021
58003023	1.062
58003024	1.013
58003025	0.993
58003026	0.969
59003011	1.052
59003012	1.032
59003013	1.029
59003014	1.019
59003015	1.014
59003016	0.990
59003021	1.043
59003022	1.016
59003023	1.043
59003024	1.034
59003025	1.006
59003026	0.983
60001111	1.131
60001112	1.031
60001113	1.067
60001114	1.081
60001115	1.042
60001116	0.984
60001121	1.112
60001122	1.061
60001123	1.106
60001124	1.020
60001125	1.004
60001126	0.954
60001211	1.047
60001212	1.001
60001213	1.042
60001214	1.039
60001215	1.015
60001216	1.029
60001221	1.050
60001222	1.040
60001223	1.033
60001224	1.007
60001225	0.994
60001226	0.975
60003111	1.016
60003112	1.021
60003113	1.087
60003114	1.093
60003115	1.108
60003116	1.028
60003121	1.111
60003122	1.052
60003123	1.123
60003124	0.989
60003125	1.017

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
60003126	0.924
60003211	1.021
60003212	1.010
60003213	1.001
60003214	1.027
60003215	1.016
60003216	1.005
60003221	1.047
60003222	1.005
60003223	1.031
60003224	1.000
60003225	1.000
60003226	1.000
60102011	0.958
60102012	1.005
60102013	1.000
60102014	1.026
60102015	0.991
60102016	0.998
60102021	0.993
60102022	0.989
60102023	0.966
60102024	0.957
60102025	0.936
60102026	0.963
61001111	1.042
61001112	1.003
61001113	1.100
61001114	1.052
61001115	1.034
61001116	0.999
61001121	1.086
61001122	1.072
61001123	1.058
61001124	1.047
61001125	0.994
61001126	0.955
61001211	1.091
61001212	0.983
61001213	1.025
61001214	1.026
61001215	1.006
61001216	1.007
61001221	1.045
61001222	1.014
61001223	1.012
61001224	1.000
61001225	0.949
61001226	0.977
61003111	1.119
61003112	0.954
61003113	0.992
61003114	1.070
61003115	1.033
61003116	0.970
61003121	1.030
61003122	0.980
61003123	1.010
61003124	0.999
61003125	0.940
61003126	0.972
61003211	0.957
61003212	0.971
61003213	1.036
61003214	1.021
61003215	0.973
61003216	0.994
61003221	0.986
61003222	0.989
61003223	1.011
61003224	1.003
61003225	1.016
61003226	1.001
62003011	1.033
62003012	0.978
62003013	1.064
62003014	1.019
62003015	1.016

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
62003016	1.020
62003021	1.022
62003022	1.012
62003023	1.032
62003024	1.032
62003025	1.002
62003026	1.008
62705011	1.088
62705012	1.054
62705013	1.090
62705014	1.062
62705015	1.021
62705016	1.006
62705021	1.095
62705022	1.066
62705023	1.074
62705024	1.030
62705025	1.024
62705026	1.002
65003011	1.017
65003012	0.999
65003013	1.030
65003014	1.014
65003015	1.002
65003016	1.003
65003021	1.011
65003022	1.012
65003023	1.008
65003024	0.995
65003025	0.992
65003026	0.997
66003011	1.017
66003012	0.988
66003013	1.023
66003014	1.034
66003015	0.999
66003016	0.972
66003021	1.013
66003022	1.008
66003023	1.000
66003024	1.018
66003025	0.978
66003026	1.002
68003011	1.005
68003012	0.977
68003013	1.028
68003014	1.008
68003015	1.008
68003016	0.997
68003021	1.003
68003022	1.005
68003023	1.019
68003024	0.997
68003025	0.988
68003026	0.987
69003011	0.991
69003012	0.981
69003013	1.019
69003014	0.987
69003015	0.986
69003016	0.997
69003021	0.984
69003022	0.981
69003023	1.014
69003024	0.982
69003025	0.982
69003026	0.995
71003111	1.064
71003112	0.995
71003113	1.107
71003114	1.054
71003115	1.041
71003116	0.997
71003121	1.007
71003122	1.015
71003123	1.012
71003124	0.981
71003125	0.996

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
71003126	0.940
71003211	0.987
71003212	0.980
71003213	1.021
71003214	0.992
71003215	0.996
71003216	0.981
71003221	1.005
71003222	1.026
71003223	1.004
71003224	0.994
71003225	1.000
71003226	0.988
71005011	1.110
71005012	1.030
71005013	1.080
71005014	1.049
71005015	1.037
71005016	1.011
71005021	1.095
71005022	1.072
71005023	1.077
71005024	1.035
71005025	1.022
71005026	1.009
72003011	1.003
72003012	1.006
72003013	1.060
72003014	1.011
72003015	1.003
72003016	1.010
72003021	1.038
72003022	0.990
72003023	1.067
72003024	1.007
72003025	1.001
72003026	1.014
72505011	1.116
72505012	1.045
72505013	1.101
72505014	1.091
72505015	1.038
72505016	1.021
72505021	1.114
72505022	1.068
72505023	1.084
72505024	1.091
72505025	1.027
72505026	1.023
75003011	1.011
75003012	1.013
75003013	1.028
75003014	1.006
75003015	1.001
75003016	0.999
75003021	1.025
75003022	0.990
75003023	1.027
75003024	0.993
75003025	1.003
75003026	0.996
76003011	1.030
76003012	0.988
76003013	1.056
76003014	1.022
76003015	1.002
76003016	1.021
76003021	1.023
76003022	1.026
76003023	1.020
76003024	1.007
76003025	1.000
76003026	1.021
78003011	1.003
78003012	0.985
78003013	1.023
78003014	1.025
78003015	1.008

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
78003016	1.001
78003021	1.041
78003022	0.987
78003023	1.016
78003024	1.016
78003025	0.997
78003026	0.981
79003011	1.013
79003012	0.995
79003013	1.041
79003014	0.999
79003015	0.993
79003016	1.001
79003021	1.010
79003022	1.000
79003023	1.015
79003024	0.994
79003025	1.001
79003026	0.997
79995011	1.077
79995012	1.007
79995013	1.082
79995014	1.065
79995015	1.033
79995016	1.021
79995021	1.069
79995022	1.026
79995023	1.725
79995024	1.048
79995025	1.027
79995026	0.989
81003111	1.034
81003112	1.035
81003113	1.123
81003114	1.086
81003115	1.041
81003116	0.990
81003121	1.041
81003122	1.061
81003123	1.060
81003124	1.019
81003125	0.977
81003126	1.013
81003211	1.031
81003212	1.021
81003213	1.035
81003214	1.020
81003215	1.002
81003216	0.986
81003221	1.031
81003222	1.020
81003223	1.045
81003224	1.003
81003225	0.990
81003226	0.980
82003011	1.017
82003012	1.017
82003013	1.071
82003014	1.014
82003015	0.978
82003016	0.975
82003021	1.030
82003022	1.021
82003023	1.064
82003024	0.998
82003025	0.987
82003026	0.982
83005011	1.066
83005012	1.023
83005013	1.107
83005014	1.063
83005015	1.027
83005016	1.005
83005021	1.058
83005022	1.055
83005023	1.077
83005024	1.025
83005025	0.973

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
83005026	1.004
87003011	1.022
87003012	1.008
87003013	1.076
87003014	1.023
87003015	0.988
87003016	0.986
87003021	1.026
87003022	0.984
87003023	1.022
87003024	1.000
87003025	0.971
87003026	0.985
88003011	1.021
88003012	1.032
88003013	1.059
88003014	1.026
88003015	0.990
88003016	0.993
88003021	1.036
88003022	1.028
88003023	1.036
88003024	0.996
88003025	0.971
88003026	0.995
89003011	1.050
89003012	1.027
89003013	1.077
89003014	1.036
89003015	1.031
89003016	1.003
89003021	1.046
89003022	1.049
89003023	1.041
89003024	1.024
89003025	1.017
89003026	1.014
89995011	1.110
89995012	1.076
89995013	1.123
89995014	1.070
89995015	1.039
89995016	1.062
89995021	1.106
89995022	1.084
89995023	1.105
89995024	1.057
89995025	1.076
89995026	1.049
90003111	1.043
90003112	1.076
90003113	1.098
90003114	1.094
90003115	1.004
90003116	0.963
90003121	1.047
90003122	1.056
90003123	1.089
90003124	1.014
90003125	1.015
90003126	0.977
90003211	1.017
90003212	1.043
90003213	1.022
90003214	1.011
90003215	1.000
90003216	1.012
90003221	1.037
90003222	1.041
90003223	1.019
90003224	1.031
90003225	1.000
90003226	0.995
90301111	1.142
90301112	1.075
90301113	1.115
90301114	1.124
90301115	1.127

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
90301116	0.971
90301121	1.105
90301122	1.020
90301123	1.089
90301124	1.008
90301125	0.971
90301126	0.960
90301211	1.160
90301212	1.056
90301213	1.128
90301214	1.116
90301215	1.094
90301216	1.013
90301221	1.132
90301222	1.070
90301223	1.108
90301224	1.074
90301225	1.042
90301226	1.054
90302111	1.093
90302112	1.055
90302113	1.159
90302114	1.095
90302115	1.088
90302116	0.992
90302121	1.055
90302122	1.080
90302123	1.106
90302124	1.035
90302125	1.030
90302126	1.007
90302211	1.052
90302212	1.000
90302213	1.042
90302214	1.004
90302215	0.990
90302216	0.990
90302221	1.029
90302222	1.016
90302223	1.094
90302224	1.025
90302225	0.971
90302226	0.995
90304111	1.047
90304112	1.053
90304113	1.147
90304114	1.090
90304115	1.074
90304116	1.046
90304121	1.069
90304122	1.060
90304123	1.068
90304124	1.074
90304125	0.981
90304126	1.057
90304211	1.076
90304212	1.052
90304213	1.071
90304214	1.065
90304215	1.028
90304216	1.029
90304221	1.070
90304222	1.072
90304223	1.079
90304224	1.026
90304225	1.033
90304226	1.029
91003111	1.035
91003112	1.045
91003113	1.112
91003114	1.073
91003115	1.020
91003116	0.986
91003121	1.000
91003122	1.033
91003123	1.045
91003124	1.020
91003125	0.947

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
91003126	0.959
91003211	1.025
91003212	0.978
91003213	1.017
91003214	1.020
91003215	1.004
91003216	0.999
91003221	1.038
91003222	1.030
91003223	1.092
91003224	1.023
91003225	1.001
91003226	0.988
92003011	1.041
92003012	1.005
92003013	1.070
92003014	1.016
92003015	0.992
92003016	0.983
92003021	0.987
92003022	1.011
92003023	1.028
92003024	1.010
92003025	0.985
92003026	0.973
95003011	1.028
95003012	0.995
95003013	1.050
95003014	0.971
95003015	1.001
95003016	0.979
95003021	1.051
95003022	1.002
95003023	1.029
95003024	0.995
95003025	0.987
95003026	0.967
96003011	1.026
96003012	1.039
96003013	1.014
96003014	1.018
96003015	1.070
96003016	1.002

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
96003021	1.043
96003022	1.108
96003023	1.065
96003024	1.030
96003025	1.010
96003026	0.976
97001011	1.251
97001012	1.235
97001013	1.250
97001014	1.278
97001015	1.180
97001016	1.117
97001021	1.199
97001022	1.158
97001023	1.182
97001024	1.136
97001025	1.111
97001026	1.112
97002011	1.092
97002012	1.084
97002013	1.088
97002014	1.085
97002015	1.048
97002016	1.014
97002021	1.088
97002022	1.071
97002023	1.079
97002024	1.052
97002025	1.061
97002026	1.018
97004011	1.026
97004012	0.992
97004013	1.048
97004014	1.009
97004015	0.993
97004016	0.963
97004021	1.063
97004022	0.990
97004023	1.053
97004024	1.011
97004025	0.932
97004026	0.974
98003011	1.044

ATTACHMENT 3.—ADJUSTMENT FACTORS BY POST STRATUM [1]—Continued

Stratum code	Factor
98003012	1.027
98003013	1.053
98003014	1.009
98003015	0.996
98003016	0.967
98003021	1.052
98003022	1.024
98003023	1.045
98003024	1.010
98003025	0.994
98003026	1.009
98904011	0.995
98904012	1.008
98904013	1.033
98904014	1.029
98904015	0.985
98904016	0.973
98904021	0.996
98904022	1.013
98904023	1.025
98904024	1.008
98904025	0.985
98904026	0.942
99003011	1.028
99003012	1.036
99003013	1.043
99003014	1.024
99003015	1.005
99003016	0.994
99003021	1.029
99003022	1.020
99003023	1.048
99003024	1.019
99003025	1.016
99003026	0.996

[1] See Attachment 2 for description of post stratum codes.

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federal register

Monday
July 22, 1991

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 333 and 369

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333 and 369

[Docket No. 75N-183F]

RIN 0905-AA06

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of an amended tentative final monograph that would establish conditions under which over-the-counter (OTC) first aid antiseptic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking to amend the previous notice of proposed rulemaking on topical antimicrobial drug products after considering that rulemaking and public comments on it. (See the **Federal Register** of January 6, 1978, 43 FR 1210.) This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by January 21, 1992. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 180 days for comments and objections instead of the normal 60 days. New data by July 22, 1992. Comments on the new data by September 22, 1992. Written comments on the agency's economic impact determination by January 21, 1992.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 13, 1974 (39 FR 33103), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial I Drug Products (Antimicrobial I Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by November 12, 1974. Reply comments in response to comments filed in the initial comment period could be submitted by December 12, 1974. In response to numerous requests, the agency issued a notice in the **Federal Register** of October 17, 1974 (39 FR 37066) granting an extension of the deadline for comments until December 12, 1974, and for reply comments until January 13, 1975.

In the **Federal Register** of January 6, 1978 (43 FR 1210), FDA published, under § 330.10(a) (7), a notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, based on the recommendations of the Antimicrobial I Panel and the agency's response to comments submitted following publication of the advance notice of proposed rulemaking.

Interested persons were invited to submit objections or requests for oral hearing by February 6, 1978. In response to numerous requests to extend the time period for submitting objections or requests for oral hearing, the agency issued a notice in the **Federal Register** of February 3, 1978 (43 FR 4637) granting an extension of the deadline to March 6, 1978.

During this time period, the agency received 6 petitions that requested reopening the administrative record and 11 requests for an oral hearing. In a notice published in the **Federal Register** of March 9, 1979 (44 FR 13041), the agency deferred action on the requests for a hearing, but granted the petitions to reopen the record to allow interested persons to submit comments and any new or additional data by June 7, 1979, and reply comments by July 9, 1979. FDA also stated its intent to publish an updated (amended) tentative final monograph based on the review and evaluation of new submissions and a reevaluation of existing data.

In a notice published in the **Federal Register** of October 26, 1979 (44 FR 61609), the agency again reopened the administrative record for the submission of new data by March 26, 1980, and for comments on the new data by May 27, 1980. This action was taken to permit manufacturers to submit the results of testing to FDA as expeditiously as possible prior to establishment of a final monograph.

Subsequent to the June 7, 1979 closing date for the submission of new data, and prior to the October 26, 1979 reopening of the administrative record, data and information were submitted to FDA. In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18398), the agency advised that it had reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the administrative record on the tentative final monograph had officially closed on March 6, 1978. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In a notice published in the **Federal Register** on January 5, 1982 (47 FR 436), the agency advised that it had again reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) on mercury-containing drug products. Interested persons were invited to submit comments by April 5, 1982, and reply comments by May 5, 1982. FDA stated that the proceeding to develop a monograph for mercury-containing drug products would be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

In a notice published in the **Federal Register** on May 21, 1982 (47 FR 22324), the agency advised that it had again reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of the recommendations of the Miscellaneous External Panel on alcohol drug products. Interested persons were invited to submit comments by August 19, 1982, and reply comments by September 20, 1982. The notice stated that the proceeding to develop a monograph for alcohol drug products would be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

In the **Federal Register** of September 7, 1982 (47 FR 39406), FDA issued a notice to reopen the administrative record for OTC topical antimicrobial drug products to allow for consideration of the Miscellaneous External Panel's recommendations on topical antimicrobial drug products used for the treatment of diaper rash. The agency discussed topical antimicrobial active

ingredients for this use in the Federal Register of June 20, 1990 (55 FR 25246).

In accordance with § 330.10(a)(10), the data and information considered by the Panels were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information. In response to the previous tentative final monograph and the advance notice of proposed rulemaking for mercury-containing drug products and the advance notice of proposed rulemaking for alcohol drug products, 4 drug manufacturers' associations, 44 drug manufacturers, 1 medical device manufacturer, 1 drug distributor, 2 medical schools, 2 research laboratories, 1 law firm, and 1 consulting firm submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch (address above).

The advance notice of proposed rulemaking, which was published in the Federal Register of September 13, 1974 (39 FR 33103), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the notice of proposed rulemaking, which was published in the Federal Register of January 6, 1978 (43 FR 1210), was designated as a "tentative final monograph." The present document is also designated as a "tentative final monograph." The legal status of each tentative final monograph, however, is that of a proposed rule.

This antimicrobial rulemaking is broad in scope, encompassing products that may contain the same active ingredients, but are labeled and marketed for different intended uses. For example, one group of products is primarily used by consumers for "first aid" and includes skin antiseptics, skin wound cleansers, and skin wound protectants. Another group of products is used by consumers on a more frequent, even daily basis, and includes products for personal use in the home, such as when caring for invalids and during family illness. Still a third group of products is generally intended for use by health professionals and includes health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs.

In order to expedite the completion of the first aid section of the antimicrobial monograph, the agency is publishing a separate tentative final monograph for these products. The non-first aid uses of topical antimicrobials will be addressed in a future issue of the Federal Register. Although the amended tentative final monographs for first-aid antiseptics and non-first aid uses of topical antimicrobials are being published separately, both categories will eventually be included under part 333 (21 CFR part 333).

The agency also has decided that OTC topical antimicrobial and topical antibiotic drug products should be included within the same monograph. Although an advance notice of proposed rulemaking to establish a monograph for OTC topical antibiotic drug products was published under part 342 (21 CFR part 342) on April 1, 1977 (42 FR 17642), the final monograph for those products was issued on December 11, 1987 (52 FR 47312) as a new subpart of the OTC topical antimicrobial monograph, 21 CFR part 333 subpart B—First Aid Antibiotic Drug Products.

Subpart A will cover first aid antiseptic drug products; subpart C will cover antifungal drug products; subpart D will cover acne drug products; and subpart E will cover non-first aid uses of topical antimicrobial drug products.

In this tentative final monograph (proposed rule) to establish subpart A of part 333 (21 CFR part 333), FDA states its position on the establishment of a monograph for OTC first aid antiseptic drug products only. This document addresses only those comments and data concerning the previous antimicrobial tentative final monograph that are related to "first aid uses." The agency will address all other submitted information at a later date.

This proposal constitutes FDA's reevaluation of the January 6, 1978 tentative final monograph based on the comments received and the agency's independent evaluation of the Miscellaneous External Panel's reports on OTC alcohol and mercury-containing drug products and the comments received. The following sections of the January 6, 1978 tentative final monograph for topical antimicrobial drug products are being addressed in this document: §§ 333.1, 333.3, 333.20, 333.40, 333.45, 333.65, 333.80, 333.90, 333.92, and 333.93. The following sections of the advance notice of proposed rulemaking for alcohol drug products are being addressed in this document: §§ 333.55 and 333.98. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them. (See Part I.)

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (39 FR 33103), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the Federal Register and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of

whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture. The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to these drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace. If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of January 7, 1972 (37 FR 235) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments and Reply Comments

A. General Comments

1. Two comments contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. One comment referred to statements on this issue submitted earlier to other OTC rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464 at 9471 to 9472), and in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by informal rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–698 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. Two comments expressed concern over the amount of time that would be allowed for the relabeling of products after publication of the final monograph, citing the "Statement of Inflation Impact Potential" for the tentative final monograph which allowed a period of 7 to 12 months for manufacturers to implement labeling changes. One of the comments stated that the final monograph should allow at least 12 months to implement any required labeling changes. The other comment stated that such a period would be adequate for most regular production items, but would place a hardship on manufacturers with respect to infrequently produced products (e.g., once a year) and slow-moving items. This comment suggested an approach that would require all new labels ordered to comply in 6 months, all labels placed on products to comply in 18 months, and labels on all products shipped to comply in 24 months. The comment stated that this approach would allow labeling inventories for infrequently produced and slow-moving items to be depleted and would accommodate the agency's objectives and minimize the cost burden imposed on manufacturers and ultimately on consumers.

The agency agrees that a reasonable period of time should be provided for relabeling. As discussed more fully in the preamble of this document, the agency is proposing to extend this period so that the final monograph will be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that, within this time, most manufacturers can have their products, including those infrequently produced, in compliance with the final monograph.

3. One comment expressed concern that scientific interpretations of testing data may differ between pharmaceutical manufacturers and FDA staff. The comment requested that the OTC drug review procedures provide an opportunity for a hearing prior to a final decision on a petition to reclassify an OTC drug product from Category III to Category I when genuine factual or scientific issues are raised concerning a drug's conformity with an OTC drug monograph.

This comment was submitted before the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). Before this decision was rendered, the OTC drug review procedural regulations in 21 CFR 333.10 allowed the continued marketing and testing of a Category III condition after a final monograph had been issued. Because of the court decision in *Cutler* v. *Kennedy*, the agency revised the OTC drug review procedural regulations so that all Category III testing must be completed prior to publication of a final monograph, if a manufacturer wants to upgrade a condition to Category I before the establishment of a final monograph. (See "Revision of Procedures Relating to Category III; Final Rule," published in the **Federal Register** of September 29, 1981, 46 FR 47730.)

Along with the publication of these revised procedures, the agency published a policy statement that provides for an exchange of information, including agency "feedback," on Category III test data between the agency and pharmaceutical manufacturers prior to publication of a final monograph. (See "Over-the-Counter (OTC) Drug Review Policy Statement," published in the **Federal Register** of September 29, 1981, 46 FR 47740.) The agency acknowledges that scientific interpretations of testing data may differ and believes that this "feedback" policy affords an adequate mechanism for pharmaceutical manufacturers and FDA to discuss air interpretations of testing data prior to a final monograph. In addition, under § 330.10(a)(7) interested parties may request an oral hearing after publication of a tentative final monograph. The agency believes that the existing regulations and the new "feedback"

policy provide adequate opportunities for pharmaceutical manufacturers to discuss data interpretations with FDA.

4. One comment stated that the agency should initiate revocation of new drug applications (NDA's) for products covered by the antimicrobial monograph upon publication of the final monograph. The comment contended that this would end continued use of claims that were approved under the NDA but are prohibited by the monograph, thus avoiding inequities in the industry and confusion in the marketplace.

The agency agrees with the comment that inequities and confusion should be avoided. After a final rule for OTC first aid antiseptic drug products is published, but before it becomes effective, the agency intends to publish in the **Federal Register** a notice of opportunity for hearing on a proposal to withdraw approval of new drug applications for products within the scope of the final monograph for OTC antimicrobial drug products.

5. One comment requested that Category III drugs be placed in Category I because they have already been extensively tested and have long been proven in the marketplace. According to the comment, if manufacturers consider it economically unfeasible to conduct the extensive Category III tests (43 FR 1210 at 1239 to 1245) the public would subsequently be deprived of drugs that it has found beneficial for self-medication for many decades. The comment stated that any currently marketed OTC drug that may later be proven unsafe, or whose claimed indications may be shown to be unwarranted, may be properly placed in Category II. However, the comment concluded that OTC drugs for which the Panel or the agency is merely seeking additional data should not be deleted from Category I while such data are being sought.

If the agency has classified an ingredient in Category III, it is because the available data are insufficient to classify the ingredient as generally recognized as safe and effective. Such ingredients cannot appropriately be put in Category I unless sufficient additional data are submitted to the rulemaking. This comment was submitted before the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979), in which the OTC drug review procedural regulations in 21 CFR 333.10 that allowed the continued marketing and testing of a Category III condition after a final monograph were declared invalid. As stated in comment 3, because of this court decision, the agency has revised the OTC drug review procedural regulations so that all Category III testing must be completed prior to publication of a final monograph. Thus, it is not possible for the agency to affirmatively permit Category III drugs, which will be considered nonmonograph conditions, to remain on the market after the final monograph becomes effective, even if additional testing is being conducted to obtain data to support a Category I or monograph classification.

6. One comment stated that "removal from the marketplace of products which have been placed in Category II such as iodine, and the failure to include in the monograph various substances that have proven themselves in the marketplace for many years, will inevitably require the public to resort to more expensive but unnecessary substitutes."

The agency is proposing that several OTC topical antimicrobial ingredients, which have been in the marketplace for many years, be reclassified as Category I in this tentative final monograph under the new category "first aid antiseptic." Thus, these ingredients, including iodine, would not have to be removed from the marketplace. Previously marketed ingredients that have not been demonstrated to be safe and effective for any OTC use and that, therefore, are not included in any OTC drug monograph cannot legally be marketed without an approved application. The economic impact of this amended proposed rule on first aid antiseptic drug products is discussed elsewhere in this document.

7. One commenter pointed out that under "Subpart B—Active Ingredients" of the 1978 tentative final monograph, no CFR part number was assigned to the category "skin antiseptic." However, part numbers were assigned to other categories without any Category I ingredients, with the term "reserved" in parentheses. The comment requested that this omission be corrected in the amended tentative final monograph.

The omission pointed out by the comment was an oversight. However, it is no longer necessary to assign a CFR part number to the category "skin antiseptic," because skin antiseptics have been included in the broader category identified in this tentative final monograph as first aid antiseptics. (See comment 13.) All Category I first aid antiseptic active ingredients have been listed in the amended tentative final monograph under subpart A, § 333.10.

8. One comment submitted the final report of a 24-month study on the chronic toxicity of triclocarban as a petition to reopen the administrative record. Several comments had previously requested an extension of time from the March 26, 1980 deadline for the closing of the administrative record for submission of new data on conditions classified in Category III in the tentative final order, stating that the submission of the final report on the ongoing 2-year triclocarban toxicity study would not be completed by this deadline. The comments requested that the deadline for submission of new data be extended until the submission of this final report or, in the alternative, that FDA assure that the final report would be accepted and considered in this amended tentative final monograph.

In the notice of proposed rulemaking (43 FR 1210 at 1233), the agency requested that a 24-month study on the chronic toxicity of triclocarban be repeated. In response to this request, another 24-month study was initiated promptly, but because of the 2-year duration of the study, the final report was not submitted to the agency until May 27, 1981. To make this amended notice of proposed rulemaking as complete as possible, the agency has included the final report of the study in the administrative record and has considered the results of this study elsewhere in this document. (See comment 47.) Thus, the comment's request to extend the deadline for the submission of new data relating to triclocarban has been granted.

B. General Comments on Antimicrobials

9. Several comments objected to some of the specific statements of identity, e.g., "skin wound cleanser," "skin wound protectant," and "skin antiseptic." One comment stated that the word "skin" was superfluous because all OTC antiseptics are intended only for use on the skin. Another comment contended that the statement of identity "antiseptic" is preferable to "skin antiseptic" because these products are used on cuts, scratches, and mucous membranes as well as skin. One comment questioned whether consumers understand the statement of identity "skin wound protectant" and recommended that FDA adopt more familiar terminology, such as "first aid product." Other comments requested that Category I skin wound cleansers or skin wound protectants that contain antimicrobial ingredients be allowed a statement of identity that recognizes their antimicrobial activity, such as "first aid skin antiseptic," "minor antiseptic," "mild antiseptic," or "antimicrobial skin wound cleanser."

Based upon the comments, the agency believes that more familiar terminology could be used as the statement of identity and that the word "skin" should

not be required in the statement of identity for these products. In reviewing the indications recommended by the Panel for skin antiseptics, skin wound protectants, and skin wound cleansers, the agency identified the phrase "first aid product" as common to these drug categories. "First aid" is also a term that is frequently included in the labeling of OTC topical antiseptic drug products, reflects the intended OTC use of these products, is more familiar terminology to consumers, and is readily understood by consumers. Therefore, the agency is proposing the term "first aid antiseptic" as the statement of identity for OTC topical antimicrobial active ingredients included in this tentative final monograph. The agency has no objection to the statement "first aid antiseptic for the skin" or "first aid skin antiseptic" appearing elsewhere in the labeling of these products as additional information to the consumer, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information.

10. Several comments argued that antimicrobial soap products making cosmetic claims only are not subject to regulation as OTC drugs and should not be considered in a review of drug effectiveness. The comments contended that if the intended use of antimicrobial soaps is stated solely in terms of deodorant effect, these products are not properly subject to regulation as OTC drugs. In addition, the comments stated that the OTC drug labeling requirements for antimicrobial soaps are unduly restrictive and uninformative. One comment pointed out that prior FDA regulations have recognized that personal cleanliness products (including both soaps and detergents) and underarm deodorants are cosmetic products, citing 21 CFR 720.49(c) (10) and FDA Trade Correspondence TC-26, February 9, 1940.

Some comments objected to the requirement that microbial reduction be established to demonstrate the deodorant effectiveness of OTC antimicrobial soaps because a direct correlation between bacterial reduction and the reduction of body odor has not been scientifically determined. One comment cited three studies (Refs. 1, 2, and 3) to support this contention. The comments requested that the final antimicrobial monograph apply only to antimicrobial soaps that make specific drug claims that any reference to deodorant claims be deleted from the monograph.

Other comments requested that the labeling for antimicrobial soaps be expanded to give more emphasis to the deodorant activity of these products. The comments objected to the limitation of phrases and the restrictions on the use of the phrases "reduces odor" and "deodorant soap" as well as to phraseology concerning deodorant usage in § 333.80 of the monograph.

Several comments objected to the proposed indication "antimicrobial soap" (§ 333.80(b) (1)) and requested that it either be deleted or modified to include deodorant claims. The comments contended that it is redundant and serves no purpose to require that the label of an antimicrobial soap contain the statement "antimicrobial soap" both as an indication and as a statement of identity (§ 333.80(a)).

One comment stated that this labeling requirement represents a misuse of the word "indications" because the permitted terms "antimicrobial" or "antibacterial" do not inform consumers of the intended use of the product in terms likely to be understood by the ordinary individual. The comments stated that because these labeling requirements do not adequately convey to consumers that the principal use and benefit to be derived from the use of antimicrobial soaps is the deodorant effect, these labeling requirements may not only confuse consumers but also may deny them truthful and useful information about these products.

The agency has carefully reevaluated this issue and clarifies that the OTC drug monographs promulgated under 21 CFR part 330 cover drug ingredients and indications, not cosmetic claims. The Federal Food, Drug, and Cosmetic Act (the act) principally defines a "drug" as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body * * *." (21 U.S.C. 321(g)(1)). The act defines a "cosmetic" as an article "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * *." (21 U.S.C. 321(i)(1)). The intended use of the product, therefore, determines whether the product is a "drug," a "cosmetic," or both. This intended use may be inferred from the product's labeling, promotional material, advertising, and any other relevant factor. (See, e.g., *National Nutritional Foods Association* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). A manufacturer's subjective claims of intent may be pierced to find its actual intent on the basis of objective evidence. *National Nutritional Foods Association* v. *FDA*, 504 F.2d 761, 789 (2d Cir. 1974).

The agency emphasizes that the previous tentative final monograph and this amended proposal cover only those antimicrobial products that are drugs or are both drugs and cosmetics, and are not applicable to the wide variety of products that are only cosmetics but that contain antimicrobial ingredients. The agency notes that most currently marketed antimicrobial bar soaps are not viewed by the consuming public as drugs but as products providing personal cleaning and deodorizing benefits. The agency agrees that separate regulations are required to govern the safety of cosmetic products containing antimicrobial ingredients. In comment 12 of the 1978 tentative final monograph (43 FR 1210 at 1212) the agency stated its intention not to require NDA's for products containing a Category I antimicrobial ingredient at greater than preservative levels and that make no drug claims. This position remains unchanged. Therefore, the presence of an antimicrobial ingredient does not, in and of itself, make a product a drug provided that no drug claim is made. However, the antimicrobial ingredient included in a cosmetic product may not exceed the concentration provided for in an applicable monograph.

As the comments have pointed out, the agency has in the past acknowledged "deodorancy" to be a cosmetic claim. Soap products that contain antimicrobial ingredients will be considered "cosmetics," and not "drugs," if only deodorant claims (or other cosmetic claims) are made for the products. The agency has previously stated that the mere presence of an antimicrobial ingredient in a product labeled for deodorant use, with the ingredient identified only in the ingredient list and no reference to its antimicrobial properties stated elsewhere in the labeling, would not cause the product to be considered a drug (Ref. 4).

However, any broader claims that represent or suggest a drug use for the product would subject it to regulation as a drug. For example, the agency considers terms such as "antibacterial," "antimicrobial," or "kills germs" in the labeling of deodorant soap products to imply that the product will have a therapeutic effect. Such statements would constitute a drug claim for the product. Likewise, statements in the labeling of a deodorant soap product such as "antimicrobial for deodorization" or "kills germs that

cause body odor" will cause the product to be a drug. Further, the term "active ingredient(s)" used anywhere in labeling would imply that the product possesses a drug-like property and would also cause the product to be a drug.

In summary, deodorant effectiveness and related claims in the labeling of soap products that contain antimicrobial ingredients but make only cosmetic claims will not be considered further in this document. Accordingly, the agency is deleting previously proposed § 333.80. However, if a manufacturer elects to market such a product as a drug (e.g., by including labeling as an "antimicrobial"), the product is a drug and is required to demonstrate efficacy, even if the labeling claim is only for a deodorant effect. Testing guidelines for antimicrobial claims will be addressed in an amended tentative final monograph covering non-first aid topical antimicrobial indications, to be published in a future issue of the Federal Register.

In addition, the agency did not receive any data on the use of antimicrobial soaps specifically labeled for first aid use. Consequently, antimicrobial soaps are not being included in this tentative final monograph for this use. Other drug uses (e.g., for general health care) will also be addressed in a future issue of the Federal Register.

References

(1) Prince, H.N., and J.A. Rodgers, "Studies on the Aerobic Axillary Microflora Employing a Standardized Swabbing Technique (Total Counts, Speciation and Ecological Drift)," Cosmetics and Perfumery, 89:25–30, 1974.

(2) Dravnieks, A., et al., "Influence of an Antimicrobial Soap on Various Effluents From Axillae," Journal of the Society of Cosmetic Chemists, 19:611–626, 1968.

(3) Cowen, R.A., "Relative Merits of 'In Use' and Laboratory Methods for the Evaluation of Antimicrobial Products," Journal of the Society of Cosmetic Chemists, 25:307–323, 1974.

(4) Memorandum of Meeting between Armour Dial, Inc., and FDA, March 9, 1983, coded MM0001, Docket No. 75N–0183, Dockets Management Branch.

11. One comment requested that scrubbing devices, such as brushes or sponges, that are impregnated with approved antimicrobial ingredients be included in the monograph.

Although the comment intended to address professional antimicrobial uses, the question of impregnated scrubbing devices may also be relevant to first aid uses. This amended tentative final monograph does not specifically provide for the use of devices such as brushes or sponges impregnated with antimicrobials. These devices are not included in the monograph because the monograph is intended to regulate OTC drug active ingredients, not device delivery systems, except to the extent that the method of application is important to the OTC drug's safety or effectiveness, and the device employed is legally available. Under such circumstances, the monograph may specify the use of the device for the specific drug.

The agency does not believe that it is necessary to include specific references to brush or sponge delivery systems in the first aid antiseptic monograph. If a topical antimicrobial active ingredient is used to impregnate a scrubbing device such as a brush or sponge as the method of application of the drug, the topical antimicrobial component continues to be regulated as a drug (and must conform to the applicable conditions of the final monograph if the ingredient is included in the monograph for the product's labeled indications), and the instrument must satisfy the device requirements under the act. For example, a brush impregnated with an antimicrobial active ingredient and intended for use as a first aid antiseptic must conform to the first aid antiseptic requirements included in Subpart A of this proposed monograph as well as any appropriate device requirements.

12. One comment expressed concern that the tentative final monograph failed to provide consumers with an antibacterial skin cleanser for home use. The comment noted that, in addition to professional health care personnel, many consumers have a need for cleansing products containing antibacterial agents for the purpose of promoting good individual and family hygiene. Potential uses cited for such products included: (1) To reduce bacteria on the hands and face to a greater extent than can be accomplished with ordinary soap, and to prevent accumulation of bacteria from potential sources of contamination. The following examples were cited: Cleansing oneself after changing a baby's diaper, or after assisting aged or ill members of the household with their toilet needs, and before preparing a family meal. (2) The added benefit of an antibacterial cleanser for the minute cuts and abrasions from shaving and other minor traumas. (3) The need for an antibacterial cleanser other than bar soap on local parts of the body, such as the face, because soap (alkali salts of fatty acids) can be irritating or too drying for some individuals' needs. The comment recommended a new product class under proposed § 333.90(a) (skin antiseptic) to be identified as "Antimicrobial (or Antibacterial) Personal Cleanser" with claims such as "decreases bacteria on the skin" and "contains an antibacterial agent." The comment also suggested that the 10-day maximum use limitation would not be appropriate for this product class, but use could be restricted to 5 or 10 times daily.

The agency believes that the comment's recommendation has merit; however, this document is limited in scope to first aid antiseptic drug products. The agency will address the issue of cleansing products containing antibacterial agents for the purpose of promoting good individual and family health care in the non-first aid uses segment of the amended tentative final monograph, in a future issue of the Federal Register.

C. Comments on Definitions

13. Several comments objected to the definition of "skin antiseptic" in proposed § 333.3(f): "A nonirritating, antimicrobial-containing preparation that prevents overt skin infection." The comments asserted that this definition requires total effectiveness (that is, antimicrobial activity against all infective agents), that this is an unreasonable and unrealistic definition, and that, at present, no testing methods conclusively demonstrate total effectiveness. The comments stated that the proposed definition is too restrictive and cited three definitions of an antiseptic that do not include the concept of prevention of infection (Refs. 1, 2, and 3). In addition, the comments pointed out that the statutory definition of an antiseptic (section 201(o) of the act) is not subject to the discretionary enlargement that was recommended by the agency in the tentative final monograph (43 FR 1210 at 1215). The comments submitted alternative definitions and requested that one of them be adopted. Two comments recommended the following definition of skin antiseptic: "A nonirritating antimicrobial-containing preparation that kills or inhibits the growth of microorganisms on the skin."

As discussed earlier in this document, the agency is proposing that skin antiseptics, as well as skin wound protectants and skin wound cleansers, be included in one category called "first aid antiseptics." Thus, a separate definition of "skin antiseptic" is no longer necessary, and § 333.3(f) of the previous tentative final monograph is not being included in this amended tentative final monograph. It is generally recognized that the chief purpose of a first aid antiseptic is to kill or prevent the growth of bacteria that may cause

infection. Therefore, the agency is proposing in this amended tentative final monograph to define the term "first aid antiseptic" as follows: "An antiseptic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns." The agency believes this definition is consistent with section 201(o) of the act and is more realistic than the previously proposed definition because it does not require total effectiveness against all infective agents, the concern expressed by the comments.

Regarding testing, it should be noted that the Panel expressed concern over the confusion concerning the definition and use of the term "antiseptic." The Panel believed that the definition of antiseptic had been interpreted as activity against infection or microbial sepsis (39 FR 33103 at 33114). The term "antiseptic" is comparable to accepted definitions for a disinfectant. The Panel attempted to eliminate the confusion "by developing a rigorous definition of a skin antiseptic" (39 FR 33114). The Panel stated that claims stating or implying an effect against microorganisms must be supported by controlled human studies demonstrating prevention of infection. The agency indicated in the tentative final monograph (43 FR 1210 at 1211) that the testing regimens were not intended to be more burdensome than needed to prove safety and effectiveness, as required by law. However, neither the Panel nor the agency proposed a specific protocol to test claimed "skin antiseptic" products. In the tentative final monograph, the agency proposed that the testing guidelines for products intended for use by health professionals be used (43 FR 1216). The agency continues to believe that products that meet these requirements are acceptable as "first-aid antiseptics," but it is not necessary for first aid antiseptics to meet these more rigid testing requirements for products intended for use by health professionals.

In this document, the agency is proposing a more consumer-oriented indication for first aid antiseptics than the indications previously proposed in § 333.90 for skin antiseptics. The new indication is as follows: "First aid to help" [select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against"] [select one of the following: "infection," "bacterial contamination," or "skin infection"] "in minor cuts, scrapes, and burns." Manufacturers choosing to market a first aid product with this claim need only meet the requirements specified in the proposed monograph. To assist manufacturers in meeting these requirements, the agency is also providing procedures for testing a "first aid antiseptic." (See comment 56.)

References

(1) "Webster's New Collegiate Dictionary," G. and C. Merriam Co., Springfield, MA, 1975, s.v. "antiseptic."

(2) "Dorland's Illustrated Medical Dictionary," 24th Ed., W.B. Saunders Co., Philadelphia and London, 1965, s.v. "antiseptic."

(3) Harvey, S.C., "Antiseptics and Disinfectants; Fungicides; Ectoparasiticides," in "The Pharmacological Basis of Therapeutics," 5th Ed., edited by L.S. Goodman and A. Gilman, The Macmillan Co., New York, p. 988, 1975.

14. Several comments objected to the definitions of the proposed skin wound cleanser and skin wound protectant categories. One comment stated that although the Panel was only charged to evaluate antimicrobial ingredients, its recommendations for the skin wound protectants and skin wound cleansers clearly extended to nonantimicrobial ingredients. This comment recommended that FDA modify the antimicrobial monograph to make it clear that it is limited to products with antimicrobial ingredients. Two comments objected to the revision in the definition of "Skin Wound Protectant" in § 333.3(h) of the tentative final monograph, which states in part "* * * it provides a protective physical barrier and a chemical (antimicrobial) barrier * * *." The comments contended that the Panel's definition of skin wound protectant in § 333.3(f) should be adopted: "A safe, non-irritating preparation applied to small cleansed wounds which provides a protective (physical and/or chemical) barrier and neither delays healing nor favors the of micro-organisms."

One comment requested that FDA include recommendations on the safety and effectiveness of the nonantimicrobial ingredients that act as physical barriers in skin wound protectants. Another comment submitted data on a cream physical barrier product without a claimed active antimicrobial agent to show that the product is safe and nonirritating, provides a protective barrier, does not delay wound healing or favor the growth of microorganisms, and therefore meets all of the criteria for a skin wound protectant as defined by the Panel (Ref. 1). This comment argued that the addition of an antimicrobial ingredient cannot contribute to the claimed effectiveness of this product when all of the efficacy criteria have been met without it. The comment concluded that FDA should either return to the Panel's definition, which does not require a chemical barrier, or modify the definition and testing required for a skin wound protectant in the previous tentative final monograph in such a way that the antimicrobial ingredient will contribute to the claimed efficacy of the product.

The agency agrees with the comment that contended that skin wound cleansers and skin wound protectants without active antimicrobial ingredients do not fall within the scope of the antimicrobial rulemaking. This amended tentative final monograph applies to products containing antimicrobial ingredients for first aid antiseptic use. As discussed in comment 13, the definitions for skin wound cleanser and skin wound protectant are no longer included in this amended tentative final monograph. The agency will discuss the data submitted by the comment for a product containing no antimicrobial ingredient, but with protective claims, in the rulemaking for OTC skin protectant drug products, in a future issue of the **Federal Register**.

Reference

(1) Comment No. C00107, Docket No. 75N-0183, Dockets Management Branch.

D. Comments on Labeling

15. Several comments contended that FDA does not have the authority to restrict OTC labeling claims to exact wording, to the exclusion of what the comments described as other "equally truthful claims for the products." One comment pointed out that numerous other meaningful and truthful statements will provide useful information and will enhance the safe and effective use of these products. Several comments maintained that manufacturers have a constitutional right to use any truthful, nonmisleading labeling under the first amendment. To support their position, the comments cited *Bigelow* v. *Virginia*, 421 U.S. 809 (1975); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); *Linmark Associates, Inc.* v. *Willingboro*, 431 U.S. 85 (1977); *Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977); *Federal Trade Commission* v. *Beneficial Corp.*, 542 F.2d 611, 97 S. Ct. 1679 (1977); and *Warner-Lambert Co.* v. *Federal Trade Commission*, 562 F.2d 749 at 768 (D.C. Cir. 1977).

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC

drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g).

In the previous tentative final monograph, supplemental language relating to indications had been proposed and captioned as "*Other allowable statements*" in §§ 333.90, 333.92, and 333.93. Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph.

In preparing this amended tentative final monograph, the agency has reevaluated these "other allowable statements" to determine whether they should be incorporated, wherever possible, as part of the indications developed under the monograph. The "*Other allowable statements*" proposed in the previous tentative final monograph that are covered by this amended tentative final monograph appeared in § 333.90(b)(2) for skin antiseptic, in § 333.92(b)(2) for skin wound cleanser, and in § 333.93(b)(2) for skin wound protectant. The statement "provides a protective physical (and chemical) barrier" proposed for a skin wound protectant has been deleted in this tentative final monograph because it does not fall within the scope of the antimicrobial rulemaking. (See comment 14.) Other previously proposed "*Other allowable statements*" are discussed in comment 16.

16. Two comments suggested that the following labeling claims would be appropriate for first aid antiseptics: "degerms," "kills germs," "kills bacteria," "bactericidal" (if applicable as, for example, for alcohol), "contains antimicrobial ingredients," "microbiocidal," "first aid product," and "reduces the risk of infection." One of the comments argued that the labeling claims "prevents overt infection" or "controls infection" should be permitted if appropriate additional studies are provided.

Other previously proposed "*Other allowable statements,*" i.e., "contains antibacterial ingredient(s)," "contains antimicrobial ingredient(s)," "does not delay wound healing," and "nonirritating" are similar to the claims suggested by the comments, and the agency is evaluating all of these statements concurrently. The OTC drug review program establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. One aspect of the program is to develop standards for certain parts of the labeling of OTC drug products. FDA has found that it is simply not practical—in terms of time, resources, and other considerations—to set standards for all labeling found on OTC drug products. Accordingly, OTC drug monographs directly address only those labeling items that are related in a significant way to the safe and effective use of covered products by lay persons. These labeling items are the product statement of identity; names of active ingredients; indications for use; directions for use; warnings against unsafe use, side effects, and adverse reactions; and claims concerning mechanism of drug action.

The agency finds that most of the terms suggested by the comments and previously proposed as "*Other allowable statements,*" while descriptive of the action of first aid antiseptic products, do not relate in a significant way to the safe and effective use of these products and, therefore, are outside the scope of the monograph.

However, the OTC drug review is also intended to ensure that OTC drug products are not misbranded. Therefore, the agency evaluates claims made on OTC drug product labels on a product-by-product basis, under section 502 of the act (21 U.S.C. 352), to determine whether those claims are false or misleading. Any claim that is outside the scope of the monograph, even though it is truthful and not misleading, may not appear in any portion of the labeling that is required by the monograph. Such a claim also may not detract from the required information. Therefore, the claims requested by the comments or previously proposed as "*Other allowable statements,*" except for those discussed below, may be included on the labeling of first aid antiseptic drug products provided that they are not intermixed with labeling established by the monograph and that they are not false or misleading.

The agency does not believe the average consumer would understand the word "overt" in the phrase "prevents overt infection." As for the phrase "controls infection," the agency believes it may mislead the consumer into assuming the product is intended for use in treating an existing infection. The agency is proposing "helps prevent infection" as a suitable alternative to the two phrases above.

The agency believes that claims such as "degerms," "degerming," "kills germs," "kills bacteria," "bactericidal," and "microbiocidal" could be potentially misleading to the average consumer if directly associated with the term "infection" that is included in the indication because the terms "kill" and "-cidal" may be interpreted to imply elimination of all bacteria on the skin when, in fact, topical antiseptics used on the skin only decrease the number of certain bacteria. However, the agency acknowledges that these terms are familiar to the average consumer and may be useful in describing the product's action or intended effect. Although these terms are not included in the monograph, they may be included in labeling that is not intermixed with monograph labeling as described above.

17. One comment requested that the following phrases (or their equivalent) be added to the monograph: Under proposed § 333.92(b)(1), "to clean and kill germs in superficial wounds," and under proposed § 333.92(b)(2), "contains a safe and effective germ-killing active ingredient." The comment also suggested that the indication "contains antimicrobial ingredient," in proposed § 333.92(b)(2) for skin wound cleansers, be expanded to provide a lay definition of "antimicrobial ingredient" because most consumers would not fully understand the meaning of the statement.

The skin wound cleanser category (proposed § 333.92) is not included in this amended antimicrobial tentative final monograph. As discussed in comment 13, all antimicrobial-containing products to be used on minor cuts, scrapes, and burns are now included in a single category, i.e., first aid antiseptic drug products.

The agency has considered the comment's request to include additional phrases to expand and clarify the meaning of "antimicrobial ingredient." The agency agrees with the comment that labeling should be more informative and has provided several optional statements in § 333.50 of the amended tentative final monograph. However, as discussed in comment 16, the agency believes that a number of terms, e.g., "kills germs," are descriptive but outside the scope of the OTC drug monograph. If such terms are included in labeling, they may not appear in any portion of the labeling required by the monograph and may not detract from such required information.

18. One comment from a manufacturer of a skin wound protectant requested that the claim "protects against * * * diaper rash" be added to the list of indications in proposed § 333.93(b)(1) for skin wound protectants. The comment stated that its product enjoys considerable use in the treatment of diaper rash, but that if an indication for diaper rash is not included in the monograph, the product could not be promoted for one of its primary uses.

As noted in comment 13, the skin wound protectant category is not included in the amended antimicrobial tentative final monograph. In the **Federal Register** of September 7, 1982 (47 FR 39436), the administrative record for skin protectant drug products was reopened to include the recommendations on diaper rash drug products of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) because that Panel concluded that the use of skin protectants may prevent skin irritation associated with diaper rash (47 FR 39436 at 39439).

In the tentative final monograph for OTC skin protectant diaper rash drug products, the claim "protects * * * diaper rash" was proposed as a monograph claim (June 20, 1990; 55 FR 25204 at 25232). In the tentative final monograph for OTC topical antimicrobial diaper rash drug products, no antimicrobial ingredients were proposed as Category I for the claim "helps protect against skin infection associated with diaper rash" (June 20, 1990; 55 FR 25246 at 25281). Final agency decisions will appear in the final monographs for OTC diaper rash drug products in a future issue of the **Federal Register**.

19. One comment recommended that antimicrobial soaps be allowed to make claims relating to general health care and personal hygiene similar to the claims allowed for health-care personnel handwashes. The comment stated that an antimicrobial soap will reduce bacteria or the transfer of potentially pathogenic organisms in the home, and therefore serves as a preventive health care aid in controlling diseases such as impetigo, pyoderma, and erythrasma. To inform consumers of such benefits, the comment suggested that the "other allowable statements" for antimicrobial soaps be expanded to include some of the labeling for health-care personnel handwashes in proposed § 333.85(b)(1).

The agency will address these uses of such products in a future **Federal Register** notice.

20. One comment objected to that part of the directions for use for skin wound protectants (§ 333.93(d)) that states, "After gentle washing with soap and water, * * *." The comment contended that in certain instances "gentle washing with soap and water" does not constitute acceptable medical practice, and requested that the wording should simply be "apply small amount directly to the affected area." Two comments objected to that part of the directions for use that states "May be applied 1 to 3 times daily." One comment stated that such a limitation of use should be based on the active ingredient(s). The comment recommended the following wording: "Labeling should also contain the recommended time interval (if any) between applications required to provide a protective (physical and chemical) barrier on the skin." The other comment pointed out that first aid products are intended only for single or a few applications. This comment contended that labeling that implies repeated use will be confusing to the consumer and suggested substituting labeling that does not assume repeated use.

The agency believes that first aid of small superficial wounds begins with adequate cleaning of the wound and, therefore, disagrees with the comment's suggestion to delete all references to cleaning the wound. However, because alkaline soap may not be appropriate for use on damaged tissue, the agency proposes to replace the phrase "after gentle washing with soap and water," with the phrase "clean the affected area."

Regarding the directions to use 1 to 3 times daily, such a direction is appropriate for these products, will discourage unlimited and repeated use, and yet will allow for limited applications as needed after a bath or after washing.

Therefore, the agency is proposing the following general directions for use for first aid antiseptics in § 333.50(d): "Clean the affected area. Apply a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage."

21. One comment requested that the portion of the directions for skin wound protectants in proposed § 333.93(d) that states "* * * cover with sterile gauze if desired" be deleted because covering a wound may retard healing in some cases. The comment submitted no data to support its request.

The agency agrees with the comment that it is not always desirable to cover a wound. However, rather than deleting any reference to covering a wound, the agency believes that consumers should be informed if precautions should be taken when covering a wound. For first aid antiseptics that do not require special labeling concerning bandages, the agency is proposing the directions for use stated in comment 20.

22. Objecting to the proposed warning "Do not bandage tightly" (§ 333.92(c)(4)), one comment stated that the warning does not make sense in terms of the way in which quaternary ammonium skin wound cleansers such as benzalkonium chloride are generally used. In place of the proposed warning, the comment recommended more explicit instructions for use, e.g., "Apply and let dry, before bandaging," and submitted data to support its position that occlusion of the wound with a bandage does not interfere with the safety and effectiveness of the drug (Ref. 1).

As discussed by the Panel (39 FR 33103 at 33132), quaternary ammonium compounds can be irritating to the skin, and the degree of irritation is dependent on concentration and/or occlusion. The Panel stated "There is little irritation potential with the use concentration." Nevertheless, the Panel stated that these compounds should not be covered with occlusive bandaging (39 FR 33116) and recommended the following warning: "Use of solution with occlusive dressing is not advisable." In paragraph 57 of the previous tentative final monograph (43 FR 1210 at 1219), the warning against "occlusive dressing" was revised to "Do not bandage tightly," and included in the warning for all skin wound cleansers. Upon further review of this warning, in the context of the newly proposed first aid category, the agency is proposing not to include a general warning statement, but instead to evaluate each individual ingredient to determine if there is a need for such a statement. The agency has reviewed the data on benzalkonium chloride submitted by the comment (Ref. 1) and determined that they show that occlusion of the wound with a bandage did not interfere with healing of the wound. Accordingly, the

agency concludes that the warning "do not bandage tightly," previously proposed in § 333.92(c)(4), is not necessary for this ingredient at the use concentrations provided for in the proposed monograph. Likewise, the alternate warning previously proposed in § 333.99 in the professional labeling section, i.e., "Do not use solution with occlusive dressing," is no longer being included in the tentative final monograph. The agency has also determined that these warning statements are not necessary for the other two quaternary ammonium compounds included in this monograph. Benzethonium chloride has been shown to be not irritating or sensitizing in two studies on children with diaper rash (Refs. 2 and 3). Methylbenzethonium chloride, a derivative of benzethonium chloride, has been used to prevent and treat skin irritations caused by contact with urine, feces, and perspiration, and has low toxicity and local sensitizing properties (Ref. 4).

The agency notes that first aid antiseptics containing quaternary ammonium compounds are usually applied as solutions or sprays, and agrees with the comment that more explicit directions for use relating to bandaging after applying the product would be useful to consumers. The agency is also aware that a number of other first aid antiseptic ingredients are marketed as solutions or sprays. The agency believes it is appropriate to let a solution or spray dry first before covering the area with a sterile bandage. Accordingly, the agency is incorporating this information in the directions section of this tentative final monograph.

References

(1) Unpublished Clinical Wound Healing Studies on Medi-Quik® submitted by Sterling Drug, Inc., Comment No. SUP013, Docket No. 75N–0183, Dockets Management Branch.

(a) Statistical Analysis of Data from Efficacy Study of Medi-Quik® as a Skin Wound Protectant in Humans.

(b) Studies on Medi-Quik® as a Wound Protectant.

(2) Susca, L.A., and B.G. Genting, "Treatment of Diaper Rash," New York State Journal of Medicine, 69:2858–2862, 1960.

(3) Christian, J.R., and F. Gonzalez, "Topical Treatment of Acute and Chronic Diaper Rash with Amino Acid Creme," Clinical Medicine, 80, 1961.

(4) Osol, A., and R. Pratt, "The United States Dispensatory," 27th Ed., J.B. Lippincott Co., Philadelphia, p. 186, 1973.

23. Two comments objected to the warning "This product is not for use on wild or domestic animal bites. If you have an animal bite, consult your physician immediately," that was proposed for skin antiseptics (§ 333.90(c)(2)), skin wound cleansers (§ 333.92(c)(2)), and skin wound protectants (333.93(c)(2)). One comment pointed out that skin antiseptics, skin wound cleansers, and skin wound protectants may be particularly useful for cleansing or for first aid treatment of wounds, including animal bites, when medical treatment is not immediately available.

Acknowledging that consumers should not rely solely on self-medication for animal bites, the comment suggested the following warning: "If you have an animal bite, consult your physician immediately." The other comment recommended deleting the warning for skin antiseptics in proposed § 333.90(c)(2), arguing that it is inappropriate because consumers know they cannot rely solely upon antiseptics to treat animal bites and that they should be examined by a physician. The comment further contended that including this type of warning in the labeling may cause consumers to view other important labeling statements on OTC drug products with skepticism.

The agency agrees that most consumers would know that a severe injury from an animal bite needs medical attention; however, consumers may not be as aware of the dangers of the superficial bites of small animals. Although bites from small wild or domestic animals, such as racoons or cats, may appear to be minor cuts, they can result in skin infections or possibly even in rabies. Consequently, the agency believes that an animal bite warning is necessary on OTC first aid antiseptic drug products to warn consumers against relying on self-medication for any animal bite. However, the agency believes that, rather than having a separate warning for animal bites, it is preferable to add the term "animal bites" to the warning that lists other conditions requiring medical attention. Therefore, the agency is proposing the following revised warning for first aid antiseptic drug products in § 333.50(c)(1) in this tentative final monograph: "In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor."

24. One comment objected to the proposed warnings against the use of skin antiseptics, skin wound cleansers, and skin wound protectants for more than 10 days (§§ 333.90(c)(3), 333.92(c)(3), and 333.93(c)(3)). The comment pointed out that these products are not recommended for daily use and that a warning that implies repeated use will be confusing to consumers. The comment also pointed out a discrepancy between the wording in the second sentence of the warning for skin antiseptics which states: "If the infection worsens or persists, see your physician," and the equivalent warning for skin wound cleansers and skin wound protectants, which states: "If the condition worsens or persists, see your physician." The comment maintained that the warning for skin antiseptics is confusing because it assumes that an infection has occurred when, in fact, none may have occurred, but the wound nevertheless requires medical attention. The comment suggested that all three warnings be replaced by one warning as follows: "If condition does not improve in 10 days, see your physician."

Another comment stated that the warnings in proposed § 333.93 (c)(3) and (c)(5) convey the same message. The warning in § 333.93(c)(3) states, "Do not use this product for more than 10 days. If the conditions worsen or persist, see your physician." The warning in § 333.93(c)(5) states, "If itching, redness, irritation, swelling or pain develops and persists for more than 1 week or increases, it may be a sign of infection or allergy. Discontinue use at once and consult your physician." The comment requested that this warning be deleted.

A third comment requested that alcohol drug products also be labeled with a warning to consult a physician if the condition worsens or persists for more than 1 week.

As noted in comment 13, the three categories formerly identified as skin antiseptic, skin wound protectant, and skin wound cleanser have all been included in the first aid antiseptic category, and all drugs in this category will bear the same warnings.

The agency disagrees that the statement limiting the period of use implies that the product is recommended for repeated daily use. The purpose of a statement limiting use of a product is to alert the consumer to the period of time that is reasonable for self-treatment of a condition and to convey the message that a condition that persists beyond this period should be treated by a doctor.

The agency agrees with the comments that the warnings in § 333.93 (c)(3) and (c)(5) convey the same message and that the statement in § 333.90(c)(3) "If the infection worsens or persists, see your physician" implies an existing infection and may cause confusion about when a physician should be consulted. The proposed warning in § 333.93(c)(5) could confuse consumers because it states that the user should stop using the product if itching, redness, swelling or pain develops or increases. These are the same symptoms that often occur after minor skin injury, the condition for

which topical first aid products are indicated. Therefore, for clarity, §§ 333.90(c)(3), 333.92(c)(3), and 333.93 (c)(3) and (c)(5) have been combined and revised. The proposed warning, redesignated § 333.50(c)(1)(ii), states: "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor."

In addition, the agency agrees with the comment that alcohol drug products should also bear such a warning. Although a physician may advise using an OTC topical first aid antiseptic for longer than 1 week, consumers should not self-medicate for a longer period of time without consulting a doctor. The Antimicrobial II Panel, in its advance notice of proposed rulemaking for OTC topical antibiotic drug products (42 FR 17642 at 17653), stated that "most small superficial skin wounds including burns, cuts, and abrasions will heal almost completely within 1 week." That Panel expressed concern that "continued use of a topical antibiotic preparation on an unhealed lesion may delay diagnosis and treatment of a more serious skin disease, e.g., a spreading deep bacterial infection, or a wound contaminated with foreign debris such as glass." (42 FR 17653). Because the situation involving use of first aid antiseptics is the same, the warning proposed in this document specifies 1 week rather than 10 days. A 1-week use limit also is consistent with the agency's warning in the final monograph for OTC topical first aid antibiotic drug products. (See 21 CFR 333.150(c)(2).)

25. One comment objected to the number of warnings required for skin wound protectants in proposed § 333.93 (c)(1) through (c)(7). The comment stated that multiple warnings will discourage self-treatment, confuse consumers, and force them to request professional assistance for minor ailments from an overburdened health care distribution system. The comment added that compliance with such lengthy labeling may be difficult because of lack of label space and suggested that, of the seven warnings, only the following two are essential: "For external use only" and "Do not use this product for more than 10 days. If the conditions worsen or persist, see your physician." The comment recommended deletion of all the other proposed warnings because "it is of no benefit to require the appearance of all possible warnings on the label of an over-the-counter medication."

The agency agrees that some of the warnings could be combined or revised without losing their intent. However, limiting the warnings to only the two suggested by the comment would not provide consumers with adequate information. The agency recognizes that it is not necessary or even possible to identify every improper use of a drug that could occur and to list such information on the drug label. Only those warnings that are necessary for the safe and effective use of the product should be included.

The indication for use in this amended tentative final monograph, "First aid to help prevent infection in minor cuts, scrapes, and burns," and the 1-week use limitation warning (see comment 24) should be sufficient to inform the consumer that first aid antiseptics are not to be used on longstanding skin conditions. Therefore, the warning previously proposed in § 333.93(c)(7), "Do not use on chronic skin conditions such as leg ulcers, diaper rash, or hand eczema," is not being included in this amended tentative final monograph.

In addition, the agency has combined and revised the proposed warnings in § 333.93 (c)(3) and (c)(5). (See comment 23.) The proposed warnings in § 333.93 (c)(2) and (c)(4) have also been combined. (See comment 24.) The proposed warning in § 333.93(c)(1) has been retained as suggested by the comment. The proposed warning in § 333.93(c)(6), "Do not use in the eyes," has been expanded to include "or apply over large areas of the body." This revision is in keeping with the agency-initiated change described in the tentative final monograph for OTC first aid antibiotic drug products (see 47 FR 29986 at 29998) that was finalized in the final monograph for those drug products (see 52 FR 47312 at 47324 and 21 CFR 333.50(c)(1)).

The agency believes that these changes will result in labeling that is clear to consumers and that assures safe and proper use of first aid antiseptic drug products.

26. Several comments objected to the warning for antimicrobial bar soaps in proposed § 333.80(c), "Do not use this product on infants under 6 months of age." Some comments recommended deleting the warning and submitted data to show that antimicrobial soaps containing triclosan and triclocarban are safe for use on infants (Ref. 1). Three comments argued that, contrary to the agency's conclusions at 43 FR 1213 and 1232, the data on the use of triclosan in monkey neonates should be regarded as adequate to show that triclosan is safe for human infant use (Ref. 2). The comments further argued that the warning in proposed § 333.80(c) is misleading and will have an unfavorable commercial impact because it will lead consumers to believe that antimicrobial soaps are harmful to users of all ages and therefore consumers will not purchase them. One comment requested that the warning not be required for soap bars weighing 2.5 ounces or less because of the limited space on the label for printing the warning and because these bars probably would not be used on infants over a long period of time.

The labeling section (333.70) in the advance notice of proposed rulemaking (39 FR 33103 at 33141) and the labeling section (333.80) in the tentative final monograph (43 FR 1210 at 1247) entitled "Antimicrobial soap" were intended to apply to antimicrobial bar soaps customarily used in the home. The Panel and the agency recognized that these products were primarily used to "reduce odor" and as "deodorant soaps." No directions for use were proposed in the tentative final monograph because of the known and customary conditions of use. As stated in comment 10, soaps containing antimicrobial ingredients and making only deodorant claims are considered cosmetics and thus are not being included in this amended tentative final monograph. (The regulations governing cosmetics are located in 21 CFR parts 700 to 740.) If the agency determines that cosmetic soap products containing an antimicrobial ingredient need a warning concerning use on infants under 6 months of age, the agency will propose to amend the cosmetic regulations accordingly.

This amended tentative final monograph does not include any products labeled for total body or chronic use in infants. Therefore, the labeling previously proposed in § 333.80, including the warning in § 333.80(c), is not being included in this tentative final monograph.

References

(1) Comment Nos. C00061, CP0002, SUP015, SUP018, C00099, C00109, C00115, and C00134, Docket No. 75N–0183, Dockets Management Branch.

(2) Unpublished Nonclinical Safety Data on Metabolism of Triclosan by Newborn Rhesus Monkeys, Submitted by Ciba-Geigy Corp., Comment No. C00109, Docket No. 75N–0183, Dockets Management Branch.

(3) Published and Unpublished Nonclinical Safety Data on Metabolism of Triclocarban by Infants, Submitted by Armour-Dial, Inc., Comment No. LET047, Docket No. 75N–0183, Dockets Management Branch.

E. Comments on Alcohols

27. Two comments stated that the statement of identity for alcohol drug products proposed by the Miscellaneous External Panel in § 333.98(a), "alcohol for topical antimicrobial use," would be

confusing to consumers. One comment contended that the word "topical" is not generally understood to mean pertaining to the surface, much less to be understood to relate to skin treatment. The comment added that the word "alcohol" in the statement of identity is superfluous because alcohol is already required under section 502(e) of the act (21 U.S.C. 352(e)) to be listed on the label as the active ingredient. The comment pointed out that "antiseptic for the skin" has been the statement of identity for a particular alcohol product since 1928 and that this statement of identity is meaningful to the layman in accordance with 21 CFR 201.61. The comment stated that alcohol and isopropyl alcohol products fit the definition of a skin antiseptic in § 333.3(f) and requested that the indications and directions for use for skin antiseptics in § 333.90 (b) and (d) be used for such alcohol and isopropyl alcohol products.

The other comment argued that the Panel's recommended statement of identity was unnecessary and should be deleted because other sections of the topical antimicrobial monograph already specify that antimicrobial-containing drug products (which would include alcohol and isopropyl alcohol) are to be labeled as skin wound cleansers, antiseptics, etc.

The agency is proposing to include alcohol and isopropyl alcohol in the list of antiseptic active ingredients in § 333.10 of this amended tentative final monograph with the statement of identity "first aid antiseptic." The Miscellaneous External Panel's definition of alcohols in § 333.3(k) is not being proposed in this amended tentative final monograph. Thus "topical," "skin," and "alcohol" are not needed as part of the statement of identity. (See comments 9 and 13.) However, the agency has no objection to these words appearing elsewhere in the labeling of these products as additional information to the consumer, provided they do not appear in any portion of the labeling required by the monograph and do not detract from such required information. (See comment 15.) The indications and directions for "first aid antiseptics" are discussed in comments 16, 17, 20, and 21.

28. One comment argued that the Panel's recommended monograph for alcohol drug products is in conflict with the regulations of the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) pertaining to ethyl alcohol in 27 CFR parts 211 and 212. (27 CFR parts 211 and 212 were removed in the Federal Register of June 2, 1983 (48 FR 24673). Denatured alcohol is now covered in 27 CFR parts 20 and 21.) Under the BATF regulations, denatured ethyl alcohol products containing 70 percent ethyl alcohol are required to be labeled as "Rubbing Alcohol," but under the recommended monograph the identical product could only be labeled as "Alcohol for topical antimicrobial use." The comment pointed out that the Panel itself recognized the effectiveness of alcohol for rubbing uses as well as the fact that these uses had been addressed by another regulatory agency. The comment stated that inconsistency between two regulatory agencies is not sound government policy, is economically unfeasible for manufacturers, and is confusing to consumers. The comment requested that a product that meets the requirements of 27 CFR parts 211 and 212 as well as the requirements of the monograph be allowed to be labeled as a topical antimicrobial product with rubbing indications.

The agency agrees that alcohol drug products for topical antimicrobial use can be labeled, at the option of the manufacturer, to meet both FDA's and BATF's regulations. The appropriate labeling for such a product would include the brand name of the product, if any, and the words "Rubbing Alcohol," in accordance with 27 CFR 211.188 (currently 27 CFR 20.134(e)). This regulation also provides that the manufacturer may include additional statements in the labeling. Thus, the labeling could also contain the words "first aid antiseptic," in accordance with 21 CFR 201.61(b) and proposed § 333.50(a). (See comment 27 for a discussion of "first aid antiseptic" as the statement of identity for these alcohol products.) With this labeling and the labeling proposed in the other parts of § 333.50, a product would meet the requirements of both regulations and provide fully informative labeling to consumers without burdening manufacturers.

29. Noting statements made by the Miscellaneous External Panel (47 FR 22324 at 22327), one comment stated that it appears logical that both alcohol and isopropyl alcohol products should include in their labeling statements to the effect that they "remove dirt and grime" and "do not stain the skin," and that alcohol products should be labeled to "clean and cool the skin" or work "as astringents, counterirritants, or rubefacients." The comment argued that these statements, based on the Panel's report, acknowledge that alcohol products have both cosmetic and medicinal uses and reflect the fact that products with both uses were submitted to the Panel for review.

The agency agrees with the Panel's statements at 47 FR 22327 that alcohols have a variety of uses such as cleaning and cooling the skin. However, these uses are not considered drug uses and as such are not appropriate for inclusion in an OTC drug monograph.

As discussed in comment 16, OTC drug monographs regulate only labeling related in a significant way to the safe and effective use of covered products by lay persons. The statement "does not stain the skin" is not significantly related to the safe and effective use of the product. It is thus outside the scope of the rulemaking, as are statements such as "cleaning and cooling" or "remove dirt and grime." Such statements will be evaluated by the agency on a product-by-product basis, under the provisions of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Moreover, any statement that is outside the scope of the monograph, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph and may not detract from such required information. However, terms outside the scope of the monograph may be included elsewhere in the labeling, provided they are not false or misleading.

Because this document addresses only first aid antiseptics, the therapeutic use of alcohol and isopropyl alcohol "as astringents, counterirritants, or rubefacients" will be considered in other rulemakings for external analgesic drug products and skin protectant drug products in future issues of the Federal Register. Alcohol and isopropyl alcohol were classified as Category II by the Miscellaneous External Panel in its statement on OTC astringent drug products, published in the Federal Register of September 7, 1982 (47 FR 39412 at 39425 and 39436 at 39444). The agency concurred with this classification in the tentative final monograph for OTC astringent drug products, published in the Federal Register on April 13, 1989 (54 FR 13490 at 13496).

30. One comment requested the addition of a fourth indication for alcohol active ingredients in proposed § 333.98(b) to allow use as an antibacterial handwash to avoid cross-contamination from one individual to another. The comment argued that products containing alcohols are often used as handwashes by athletic trainers to help prevent the spread of skin

infections from one individual to another in situations in which soap and water are not available, e.g., on the playing field.

Because the scope of this document is limited to first aid products, the indication requested by the comment will not be discussed here. It will be addressed in a future issue of the **Federal Register** covering antimicrobial drug products that are used as antiseptic handwashes.

31. One comment stated that the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (Dental Panel) allowed benzocaine or phenol in 70 percent ethyl alcohol for use on the gums (47 FR 22712 at 22737 and 22740). Therefore, it was inconsistent for the Miscellaneous External Panel to place the statement "For application to mucous membranes" in Category II for alcohol drug products (47 FR 22324 at 22332). The comment pointed out that the Miscellaneous External Panel recommended caution in the use of alcohols on mucous membranes in concentrations recommended for antimicrobial use (60 to 95 percent for ethyl alcohol) (47 FR 22327), but the comment did not believe that this caution necessitated an all-inclusive Category II labeling statement. The comment requested that the phrase "except in products containing specific label directions for such use" be added to make the Category II statement read, " 'For application' to mucous membranes, (except in products containing specific label directions for such use)."

An ingredient or drug product can have multiple uses and thus be reviewed by several different panels. The Dental Panel recommended that ethyl alcohol be permitted as a vehicle in concentrations up to 70 percent in products used on the teeth and gums (47 FR 22737 and 22740), but deferred the review of alcohol as an active antiseptic ingredient in the mouth and throat to the Oral Cavity Panel (47 FR 22715). The Oral Cavity Panel placed alcohol in Category III for antimicrobial use in the mouth, but stated that it was ineffective as an antimicrobial agent at concentrations less than 70 percent and that concentrations higher than 35 percent cause burning of mucous membranes (47 FR 22760 at 22872). The Miscellaneous External Panel evaluated ethyl alcohol for use as a topical antimicrobial agent on the skin. The Panel was concerned that alcohol would be irritating to mucous membranes, recommended caution in this use, and placed the statement "For use on mucous membranes" in Category II.

The indications for alcohol drug products covered by this rulemaking apply only to topical antimicrobial uses on the skin and do not include use on mucous membranes, as in the mouth. The agency will address the use of alcohol as an active ingredient on the mucous membranes of the mouth and throat in the proposed rulemaking for oral health care drug products, to be published in a future issue of the **Federal Register**. In developing its proposals in that document, the agency will consider the recommendations of the three Panels, including appropriate concentrations of alcohol in OTC drug products intended for oral use.

32. Two comments requested that small-volume, single-use products containing alcohol active ingredients be exempted from the warning, "Flammable, keep away from fire or flame." The warning was recommended by the Miscellaneous External Panel in § 333.98(c)(1)(ii) (47 FR 22324 at 22330 and 22333). One of the comments argued that swabs saturated with isopropyl alcohol contain such a minute volume of alcohol, 2.5 to 7 mL in each packet, that the warning about flammability is unnecessary for the protection of consumers and may cause undue alarm. The comment pointed out that the United States Department of Transportation excludes such products from the Hazardous Materials Regulations pertaining to flammable liquids.

This comment also requested that the Miscellaneous External Panel's recommended warning in § 333.98(c)(2) for products containing isopropyl alcohol, "Use only in a well-ventilated area; fumes may be toxic," should not be required for single-use alcohol swab products. The comment stated that this warning was proposed by the Panel based on a case in which a large volume of isopropyl alcohol was used in a poorly ventilated room. The comment argued that a large quantity of swabs saturated with isopropyl alcohol would have to be used for this type of application and this is virtually impossible.

The agency disagrees with the comments that small-volume packages containing alcohol active ingredients should be exempted from the flammability warning. The Department of Transportation finding applies only to the shipping of such products in intact packages, whereas the proposed warning informs consumers of proper use after opening the package. The warning is not intended to alarm consumers, but to caution them against improper use of the ingredients. Even small volumes of alcohol should be kept away from fire or flame. The United States Pharmacopeia (U.S.P.) states that isopropyl rubbing alcohol and rubbing alcohol should be labeled to indicate that they are flammable and are to be stored remote from heat (Ref. 1).

However, the agency agrees with the comment that the warning against use in poorly ventilated areas is not needed on small-volume products containing isopropyl alcohol. In fact, the agency tentatively concludes that such a warning is not needed for any product containing isopropyl alcohol because the labeling in this monograph limits its use, i.e., "do not * * * apply over large areas of the body." The agency has reviewed the adverse reactions upon which the Panel based its warning. The three reported cases of adverse effects (Refs. 2, 3, and 4), apparently due to inhalation of isopropyl alcohol, concerned infants in prolonged contact with isopropyl alcohol. The infants were either wrapped in towels saturated with isopropyl alcohol or the alcohol was applied in tepid sponging. The infants were found unconscious or in a stupor after 4 to 8 hours of contact with isopropyl alcohol. Complete recovery occurred on the day following the incident. These three cases, reported between 1953 and 1969, appear to be isolated, infrequent incidents. A warning similar to the one recommended by the Miscellaneous External Panel most probably would not have prevented the adverse reactions reported.

The agency is not proposing that isopropyl alcohol include a warning for toxic fumes in view of the indications provided for in this document, namely, "First aid to help prevent the risk of skin infection in minor cuts, scrapes, and burns." The agency believes that this indication makes it unlikely that anyone using the product as indicated would be exposed to alcoholic fumes for any extended time. Comments are invited on the need for such a warning, including any reports of adverse reactions due to inhalation that have not yet been brought to the agency's attention.

References

(1) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 731, 1989.

(2) Garrison, R.F., "Acute Poisoning from Use of Isopropyl Alcohol in Tepid Sponging," Journal of the American Medical Association, 152:317–318, 1953.

(3) Senz, E.H., and D.L. Goldfarb, "Coma in a Child Following Use of Isopropyl Alcohol in Sponging," Journal of Pediatrics, 53:322–323, 1958.

(4) McFadden, S.W., and J.E. Haddow, "Coma Produced by Topical Application of Isopropanol," Pediatrics, 43:622–623, 1969.

33. One comment requested that the concentration range for ethyl alcohol in proposed § 333.55 (47 FR 22324 at 22332) be broadened to include 48 percent (by volume) aqueous ethyl alcohol for the indications recommended by the Miscellaneous External Panel in § 333.98(b) (47 FR 22330 and 22332). The comment argued that a skin antiseptic does not have to be microbiocidal against all microorganisms, but only against those known to cause infection in minor cuts, scratches, and abrasions.

The comment submitted data on the microbiocidal activity of 48 percent alcohol by volume in aqueous solution and of a marketed product containing the same concentration of alcohol against a variety of micro-organisms, including *Staphylococcus aureus* (*S. aureus*), *Pseudomonas aeruginosa* (*P. aeruginosa*), *Bacillus subtilis* (*B. subtilus*), Proteus species, and *Candida albicans* (*C. albicans*) (Ref. 1). The comment stated that the minimum inhibitory and minimum biocidal activities of the alcohol solution were effective at fourfold and eightfold dilutions and the minimum inhibitory and minimum biocidal activities of the product were effective at eightfold to sixteenfold dilutions, thus indicating effectiveness even if diluted by body fluids at the wound site.

The comment pointed out that, according to the Miscellaneous External Panel, the potential of alcohol to irritate the skin increases with increasing concentration. The comment concluded that an alcohol product should have a high enough concentration to be effective as a skin antiseptic, yet be mild enough to cause minimal skin irritation.

The agency has reviewed the submitted data, which included studies to measure the minimum in vitro contact time for 48 percent alcohol to kill test micro-organisms. Cultures of test micro-organisms were mixed with the test solution containing 48 percent alcohol and subcultured at the following times: 0 (immediately after mixing), 1, 3, 5, 10, and 15 minutes. The test solution killed many test micro-organisms immediately upon contact and all micro-organisms except *B. subtilis* within 1 minute of contact time. The slight increase in time required for 48 percent alcohol to act was insignificant in terms of effectiveness.

Based on these studies and on the advance notice of proposed rulemaking for alcohol drug products (47 FR 22324), the agency proposes that 48 to 95 percent alcohol be classified as Category I. Any authorized formulation of specially denatured alcohol identified in 27 CFR Part 20 may be used. Although the 48-percent alcohol results in an increased time-to-death compared with 60 percent alcohol, the agency believes that the increase in time-to-death is not significant in products for limited first aid antiseptic use.

The agency recognizes that because of its solvent activity, alcohol is frequently used as a vehicle for first aid antiseptic ingredients as well as many other topical medications. As pointed out by the Miscellaneous External Panel (47 FR 22324 at 22327), alcohol is also capable of altering the stratum corneum (skin surface) and enhancing its permeability, thus facilitating the penetration through the skin of any ingredient that is dissolved in it (Ref. 2). For example, enhanced penetration has been demonstrated for iodine (Ref. 3). It is recognized that a wide range of ethyl alcohol concentrations have antiseptic properties (47 FR 22328). However, based upon submitted data for marketed products, only ethyl alcohol in a concentration range of 48 to 95 percent is considered to be an active concentration range for first aid antiseptic use.

The agency notes that the Miscellaneous External Panel included three indications for ethyl alcohol in § 333.98(b): (1) "For first aid use to decrease germs in minor cuts and scrapes," (2) "To decrease germs on the skin prior to removing a splinter or other foreign object," and (3) "For preparation of the skin prior to an injection." Because the agency is now proposing a new first aid antiseptic category for many ingredients, including alcohol, and a general indication, e.g., "First aid to help prevent infection in minor cuts, scrapes, and burns," the agency has not adopted the Panel's first indication. Describing the intent of a product, i.e., "help prevent infection," is more appropriate in a general indication to be included in the monograph than stating a mode of action, i.e., "decreases germs."

The agency believes that the second indication, "to decrease germs on the skin prior to removing a splinter or other foreign object," is a descriptive statement giving an example of a particular kind of first aid. Such illustrative statements are outside the scope of the monograph. Such statements will be evaluated by the agency on a product-by-product basis, under the provision of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Moreover, any statement that is outside the scope of the monograph, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph and may not detract from such required information. However, terms outside the scope of the monograph may be included elsewhere in the labeling, provided they are not false or misleading.

The third indication, "For preparation of the skin prior to an injection," will be discussed in a future Federal Register publication on non-first aid uses of antimicrobial ingredients.

References

(1) Comment No. C00142, Docket No. 75N-0183, Dockets Management Branch.

(2) Scheuplein, R. J., and I. H. Blank, "Mechanism of Percutaneous Absorption. IV. Penetration of Nonelectrolytes (Alcohols) from Aqueous Solutions and from Pure Liquids," Journal of Investigative Dermatology, 60:286–296, 1973.

(3) Reeve, T. S., G. A. E. Coupland, and I. B. Hales, "The Effect on Serum Iodine Levels of Painting Tincture of Iodine on the Skin," Medical Journal of Australia, 1: 891–892, 1973.

F. Comments on Chlorhexidine Gluconate

34. Several comments requested that the agency include chlorhexidine gluconate as a Category I ingredient in any amended tentative final monograph. The comments submitted references and data to establish general recognition of safety and effectiveness (Ref. 1) and stated that chlorhexidine gluconate solution is recognized in the "British Pharmacopeia" (Ref. 2) and is formulated in a wide range of products that have been successfully marketed to a material extent and for a material length of time in other countries. The comments asserted that when formulated in compliance with FDA's current good manufacturing practice regulations (21 CFR Part 211), chlorhexidine products are safe and effective for use as skin wound cleansers, skin wound protectants, patient preoperative skin preparations, skin antiseptics, surgical hand scrubs, and health-care personnel handwashes.

A reply comment argued that chlorhexidine gluconate, currently marketed in the United States under approved NDA's, is not eligible for an OTC drug monograph because the ingredient has not been marketed within this country to a material extent and for a material length of time. The comment added that variations in final formulations may alter the safety and effectiveness of the ingredient. The comment submitted data (Ref. 3) to support this viewpoint and requested that chlorhexidine gluconate be classified in Category II.

In the previous tentative final monograph (43 FR 1210), chlorhexidine gluconate (4 percent solution) was neither addressed nor categorized as Category I, II, or III. However, subsequent to the tentative final monograph, the agency granted a petition (Ref. 4) and in the **Federal Register** of March 9, 1979, reopened the administrative record to allow interested persons an opportunity to submit data and information (44 FR 13041). The comments (Ref. 1) and reply comment (Ref. 2) were submitted in response to that notice. However, since that time a majority of the comments on chlorhexidine submitted in response to the notice have been withdrawn (Ref. 5). While the data and information remain on public display as part of the administrative record, they are no longer being considered in this rulemaking.

The agency has reviewed the marketing history of chlorhexidine gluconate and finds that although it has been marketed for professional or hospital use, this ingredient has never been marketed in the United States for any first aid use. Accordingly, chlorhexidine gluconate 4 percent aqueous solution as a first aid antiseptic is a new drug and is not included in this proposed monograph.

The professional uses for chlorhexidine gluconate requested by the comments (Ref. 1), i.e., surgical hand scrub and health-care personnel handwash, will be addressed separately in the segment of this rulemaking dealing with uses other than first aid in a future issue of the **Federal Register.**

References

(1) Comment Nos. C00110, C00116, C00120, C00130, C00131, C00136, C00137, EXT018, RC0002, RC0005, CP0003, LET012, LET014, LET016, SUP030, SUP033, SUP038, and SUP040, Docket No. 75N-0183, Dockets Management Branch.

(2) "British Pharmacopeia," Vol. I, Her Majesty's Stationery Office, London, pp. 100-101, 1980.

(3) Comments No. RC001 and RC004, Docket No. 75N-0183, Dockets Management Branch.

(4) Citizen Petition No. CP003, Docket No. 75N-0183, Dockets Management Branch.

(5) Comments No. WDL003, WDL004, and WDL005, Docket No. 75N-0183, Dockets Management Branch.

G. Comments on Chloroxylenol

35. A number of comments disagreed with the agency's Category III classification of chloroxylenol in the tentative final monograph. They argued that reevaluation of the data previously submitted to the agency along with new data that have been submitted (Refs. 1 through 16) would provide adequate justification for classifying chloroxylenol in Category I for safety and effectiveness for use in antimicrobial soaps, health-care personnel handwashes, patient preoperative skin preparations, skin antiseptics, skin wound cleansers, skin wound protectants, and surgical hand scrubs. Several comments pointed out that the Antimicrobial II Panel unanimously concluded that chloroxylenol is generally recognized as safe for topical use in athlete's foot and jock-itch preparations. One comment stated that the Panel placed hexylresorcinol in Category I and chloroxylenol in Category III as a skin wound cleanser, but that a comparison of the available data clearly indicates that the safety data available on chloroxylenol are superior to those for hexylresorcinol.

Data submitted by the comments regarding safety and effectiveness for uses other than first aid, e.g., health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub will be discussed in the segment of this rulemaking dealing with uses other than first aid in a future issue of the **Federal Register.**

In the tentative final monograph, chloroxylenol was categorized as Category III for safety and effectiveness as a skin antiseptic, skin wound cleanser, and skin wound protectant, and it was recommended that effectiveness testing, both in vitro and in vivo, be done (43 1210 at FR 1238). The agency also requested data to show the effects of chloroxylenol on wound healing (43 FR 1238).

Subsequent to the tentative final monograph, the Antimicrobial II Panel in the advance notice of proposed rulemaking for OTC topical antifungal drug products categorized chloroxylenol (0.5 to 3.75 percent) as safe (Category I) for short-term use (up to 13 weeks) (47 FR 2480 at 12535).

The agency has reviewed the data, which include wound-healing studies, submitted by the comments. Bradbury and Hayden (Refs. 9 and 10) described studies on the effect of various concentrations of chloroxylenol up to 4.8 percent, on wound healing in rats. Wound healing was assessed by measuring wound tensile strength and histopathology. The results showed that none of the treatments significantly altered wound tensile strength or caused a significant delay in the healing process.

Maibach (Refs. 11 and 22) described two clinical studies that used the forearms of human volunteers to assess the effects of petroleum jelly and carbolated petroleum jelly, containing chloroxylenol 0.5 percent, on wound healing. In one study (Ref. 11), the forearm skin was stripped and treated twice daily for 5 days. In the other study, incisions were made in the forearm and treated three times in 24 hours (Ref. 12). There were no differences in the rates of wound healing between control sites and treated sites.

These studies (Refs. 9 through 12) showed that chloroxylenol 0.5 percent to 4.8 percent did not delay wound healing and affirm the Antimicrobial II Panel's conclusion that chloroxylenol is safe for short-term use. Accordingly, the agency is reclassifying chloroxylenol to Category I for safety for use as a first aid antiseptic.

The in vitro data demonstrate that formulated chloroxylenol, in the presence of 5 percent serum (37 °C) is effective within 5 to 10 minutes. The in vivo data, derived from studies of artificial contaminants on the skin of human test subjects, showed that chloroxylenol-containing product reduced the number of staphylocci, pseudomonas, escherichia, and streptococci by greater than one log (i.e., 1 $\log_{10}$) within 5 minutes. However, none of the studies demonstrate the contribution of chloroxylenol to the formulated product.

The agency does not consider the data regarding the antiseptic activity of chloroxylenol itself to be adequate. While the data are considered sufficient to support in vitro and in vivo effectiveness for the finished products (Refs. 13 through 16), the available data are inadequate to show the contribution of the chloroxylenol. Because these finished products contain several additional ingredients, i.e., surfactants, isopropanol, pine oil, or ethylenediaminete-tracetic acid (EDTA), any of which could have contributed germicidal activity, conclusions regarding chloroxylenol's active contribution to the products' efficacy cannot be supported. Accordingly, in this proposed rule chloroxylenol is being proposed as a Category III first aid antiseptic ingredient for effectiveness.

References

(1) Unpublished Clinical Safety and Effectiveness Studies on Aqueous Soap Formulations, submitted by the Pennwalt Corp., Comment No. 0B0007, Docket No. 75N-0183, Dockets Management Branch.

(a) Controlled Clinical Study Comparing the Activity of Fresh, Camay Soap, and Phisohex Against the Natural Bacterial Flora of the Hand.

(b) Antimicrobial Activity of PCMX, Triclosan, and TCC.

(c) Repeated Insult Patch Testing of Fresh Soap.

(2) Unpublished Nonclinical and Clinical Studies, and Protocols, submitted by the

Pennwalt Corp., Comment No. C00096, Docket No. 75N-0183, Dockets Management Branch.

(a) Part I: PCMX Toxicosis, final reports of completed studies, interim reports of incomplete studies, and Preclinical Testing Protocol.

(b) Part II: Complete Reports on Clinical Safety and Efficacy and In Vitro Efficacy Studies.

(3) Unpublished Clinical Effectiveness Studies on Aqueous Soap Formulations, submitted by Chemical Specialties, Inc., Comment No. C00122, Docket No. 75N-0183, Dockets Management Branch.

(a) Protocol and Results of a Glove Juice Hand Washing Test Performed with PHLO Antimicrobial Skin Cleanser.

(b) Results of a Zone of Inhibition and Assay Performed on Aged Samples of PHLO Antimicrobial Skin Cleanser.

(4) Unpublished Clinical Safety and Effectiveness Studies on Aqueous Soap Formulations, submitted by Sani-Fresh, Comment No. C00123, Docket No. 75N-0183, Dockets Management Branch.

(a) Bactericidal Activity of Envair Antiseptic Hand Soap.

(b) Dermal Irritation Study.

(c) Insult Patch Test.

(d) Bacterial Kill Test.

(e) Hand-wash Effectiveness Test.

(5) Unpublished In Vitro Effectiveness Studies Performed on Aqueous Soap Solutions, submitted by Seagull Chemical, Comment No. C00125, Docket No. 75N-0183, Dockets Management Branch.

(a) AOAC Available Chlorine Germicidal Equivalent Concentration Test.

(b) The Antimicrobial Activity of a Sample.

(6) Published and Unpublished Nonclinical and Clinical Safety Studies, submitted by Ferro Corp., Comment No. SUP011, Docket No. 75N-0183, Dockets Management Branch.

(7) Published and Unpublished Safety and Effectiveness Studies, submitted by Scientific and Regulatory Services, Comment No. SUP012, Docket No. 75N-0183, Dockets Management Branch.

(8) Unpublished Clinical Safety and Effectiveness Studies, submitted by Chesebrough Ponds, Inc., Comment No. SUP010, Docket No. 75N-0183, Dockets Management Branch.

(a) The Effects of Vaseline Petroleum Jelly and Vaseline First Aid Carbolated Petroleum Jelly on Epidermal Wound Healing—A Controlled Clinical Laboratory Study, April 29, 1976.

(b) The Effect of Vaseline Petroleum Jelly and Vaseline First Aid Carbolated Petroleum Jelly on Healing of Experimental Skin Wounds, January 13, 1977.

(9) Bradbury, S.J., and J. Hayden, "Effect of Dettol® on Wound Healing in Rats," Report No. RC 76132, unpublished study, Comment No. SUP05, Docket No. 75N-0183, Dockets Management Branch.

(10) Bradbury, S.J., and E.J. Hayden, "Dettol® Wound Healing," unpublished study, Project No. RC 1081, 1978, Comment No. SUP012, Docket No. 75N-0183, Dockets Management Branch.

(11) Maibach, H.I., "The Effects of Vaseline® Petroleum Jelly and Vaselines First Aid Carbolated Petroleum Jelly on Epidermal Wound Healing—A Controlled Clinical Laboratory Study," unpublished study, Comment No. SUP010, Docket No. 75N-0183, Dockets Management Branch.

(12) Maibach, H.I., "The Effect of Vaseline® Petroleum Jelly and Vaseline®First Aid Carbolated Petroleum Jelly on Healing of Experimental Skin Wounds," unpublished study, Comment No. SUP010, Docket No. 75N-0183, Dockets Management Branch.

(13) Munton, T.J., and J. Prince, "The Bacteriostatic and Bactericidal Activity of Dettol® Against a Range of Recently Isolated Mesophilic Strains Including Members of the Normal Flora and Cutaneous Pathogens of the Skin," unpublished study, No. BL 75/4, 1975, Comment No. SUP003, Docket No. 75N-0183, Dockets Management Branch.

(14) Prince, J., and K.A. Barker, "A Comparison of the In-Vitro Activity of Dettol®, Hexylresorcinol and Benzalkonium Chloride," unpublished study, No. BL 76/28, 1976, Comment No. SUP003, Docket No. 75N-0183, Dockets Management Branch.

(15) Munton, T.J., and J. Prince, "The Bactericidal Activity of Dettol® on Skin Artificially Contaminated with Micro-organisms Using the Replica Plating Technique," unpublished study, No. BL 75/14, RC 7565, 1975, Comment No. SUP003, Docket No. 75N-0183, Dockets Management Branch.

(16) "Scientific Information on the 'In-vitro' and 'In-vivo' Antimicrobial Activity of Dettol® as Determined in the Bacteriological Laboratories of Reckitt and Colman, Hull," published report, Comment No. C00062, Docket No. 75N-0183, Dockets Management Branch.

H. Comments on Hydrogen Peroxide

36. Two comments requested that hydrogen peroxide solution (3 percent) be included in the monograph as a Category I skin antiseptic. One comment pointed out that no mention of the ingredient is made in the proposed or tentative final monograph even though hydrogen peroxide has been recognized by the U.S.P. for many decades as a topical anti-infective for application to skin and mucous membranes. The comment submitted two references to show that hydrogen peroxide is a desirable skin antiseptic that can be used safely and effectively by the layman (Refs. 1 and 2).

Hydrogen peroxide solution (3 percent) for use as a skin antiseptic was not classified in the previous tentative final monograph because it was deferred to the Miscellaneous External Panel. (See comment 85, 43 FR 1210 at 1223.) A manufacturer had made a submission (Ref. 3) on hydrogen peroxide (U.S.P., 3 percent) as a first aid antiseptic drug product to the Miscellaneous External Panel but that Panel disbanded before it reviewed hydrogen peroxide. The agency subsequently concluded that it would be appropriate to categorize hydrogen peroxide as a first aid antiseptic in this antimicrobial rulemaking. Accordingly, the agency requested and received permission from the manufacturer to place the manufacturer's submission (Ref. 3) on public display in the Dockets Management Branch under the antimicrobial docket number (Ref. 4).

The submission forwarded by the manufacturer (Ref. 3) included labeling for a currently marketed product containing hydrogen peroxide solution U.S.P. 3 percent, which states: "First aid antiseptic" "For treatment of minor cuts and abrasions." The submission also included safety and effectiveness data from published articles and unpublished studies. These data indicate that hydrogen peroxide inhibits *S. aureus, Salmonella typhosa, Escherichia coli (E. coli), Proteus vulgaris, Klebsiella pneumoniae, Streptococcus hemolyticus,* and *P. aeruginosa.* The manufacturer also provided in vitro data to show that 3 percent hydrogen peroxide reduced the number of *S. aureus* ATCC 6538P by 3 logs (3 $\log_{10}$) within 5 minutes and completely inhibited all bacteria within 10 minutes.

In a separate OTC drug rulemaking, for OTC oral mucosal injury drug products, the agency found hydrogen peroxide (3 percent in aqueous solution) safe for short-term use up to 7 days. (See the **Federal Register** of July 26, 1983, 48 FR 33984 at 33993.)

Hydrogen peroxide achieves its intended benefit in vivo by means of both a mechanical action and a measurable antibacterial action. Because hydrogen peroxide has been demonstrated to be both safe and effective for use in minor wounds, the agency is proposing to classify hydrogen peroxide (3 percent in aqueous solution) as Category I for use as a first aid antiseptic drug product.

References

(1) "Antiseptics and Disinfectants," *in* "AMA Drug Evaluations," 2d Ed., American Medical Association, Publishing Sciences Groups, Inc., Ashton, MA, p. 653, 1973.

(2) Schumb, W. C., C. N. Satterfield, and R. L. Wentworth, "Hydrogen Peroxide," American Chemical Society Monograph Series, 128, Reinhold Publishing Corp., New York, 1955.

(3) OTC Volume 160031.

(4) Letter from M. Kaplan, Parke-Davis, Division of Warner Lambert and Co., to W. E. Gilbertson, FDA, dated July 12, 1982, Comment No. LET051, Authorizing Public Display of OTC Volume No. 160031, Docket No. 75N-0183, Dockets Management Branch.

I. Comments on Iodine and Iodophors

37. One comment objected to the classification of iodine tincture in Category III for use as a skin antiseptic. To justify Category I status, the comment cited the more than 130-year

history of use of iodine tincture as a household first aid product and the extensive literature on iodine as an antiseptic published during the past several decades. The comment submitted two studies to support its position (Refs. 1 and 2). According to the comment, the study by Salle and Catlin (Ref. 1) showed that iodine tincture (2 percent) has the highest germicidal activity and the lowest toxicity of the germicides tested. The comment pointed out that the publication by Gershenfeld and Witlin (Ref. 2) concluded that iodine was a highly effective bactericidal agent against many different species of microorganisms at high dilution and within a wide pH range; and that it possessed a very low toxicity to tissues as determined by many varied in vitro and in vivo toxicity tests, including tests on human skin. The comment added that an extensive list of additional references has been included as part of the cited studies, and that these references should help resolve the questions raised by the Commissioner. The comment recommended that iodine tincture be placed in Category I.

In the tentative final monograph, the agency concluded that elemental iodine hydroalcoholic solution (iodine tincture) is effective for first aid use on minor wounds as a skin antiseptic, skin wound protectant, and skin wound cleanser, although questions remained regarding the minimally effective dose and the effect of organic load and pH. In addition, the agency was concerned about the irritating properties of iodine and delay in wound healing and therefore classified iodine tincture in Category III (43 FR 1210 at 1234).

The agency has reviewed the data and information submitted by the comments (Refs. 1 and 2), which described reports from studies on the properties of elemental iodine, iodine tincture U.S.P., and iodine solution U.S.P. The studies, not previously reviewed in either the Panel report or in the tentative final monograph, provided data primarily pertaining to effectiveness.

The agency has also considered additional studies in test wounds of laboratory animals. Branemark et al. (Ref. 3) inflicted minute test wounds and control wounds in the skin of mice, hamsters, and rabbits. The test wounds were treated with iodine solutions, and the structure of the skin was observed microscopically for healing. Various antiseptic ingredients, including iodine in saline solution, were tested on minute cutaneous wounds. Microscopic analysis showed very slight tissue injury from the antiseptic.

Edlich et al. (Ref. 4) inflicted deep wounds in the skin of guinea pigs, contaminated the wounds with *S. aureus*, waited 5 minutes, cleansed the wounds with 100 milliliters (mL) of various antiseptic solutions, including 70 percent alcohol, iodine aqueous solution or iodine tincture, and saline control solutions. The wounds were closed with tape, observed, and measured for inflammatory responses (i.e., induration and pus). Subcultures were made for viable bacteria. Edlich et al. reported that 70 percent alcohol, iodine aqueous solution, and iodine tincture helped to reduce the rate of infection without causing significant inflammatory responses in the wounds. Specifically, the authors stated that "The gross infection score, the indurated wound margin, and the percentage of positive cultures in the contaminated wound receiving a single irrigation with tincture of iodine were significantly less than the corresponding inflammatory responses in the control wounds."

Based on the available data, the agency concludes that 2 percent aqueous or alcoholic solutions of elemental iodine (i.e., iodine tincture, U.S.P. or iodine topical solution, U.S.P.) are safe and effective for first aid use to decrease the number of bacteria in minor cuts and scrapes. Therefore, the agency is proposing that these iodine solutions be Category I for use as a first aid antiseptic.

References

(1) Salle, A. J., and B. W. Catlin, "Profile Evaluations of Germicides," *Journal of the American Pharmaceutical Association*, (Scientific Edition), 36:129–133, 1947.

(2) Gershenfeld, L., and B. Witlin, "Iodine as an Antiseptic," Annals of the New York Academy of Sciences, 53:172–182, 1950.

(3) Branemark, P. J., et al. "Tissue Injury Caused by Wound Disinfectants," Journal of Bone and Joint Surgery, 49:48–62, 1967.

(4) Edlich, R. F., et al., "Studies in Management of the Contaminated Wound, III. Assessment of the Effectiveness of Irrigation with Antiseptic Agents," The American Journal of Surgery, 118:21–30, 1969.

38. A number of comments submitted new data (Ref. 1) to establish that povidone-iodine is safe and effective as a topical antimicrobial drug. The comments requested that povidone-iodine be reclassified from Category III to Category I as a topical antimicrobial ingredient for use as an antimicrobial soap, health-care personnel handwash, surgical hand scrub, patient preoperative skin preparation, skin antiseptic, skin wound cleanser, and skin wound protectant.

The agency has considered the new povidone-iodine data submitted in support of the request to reclassify povidone-iodine from Category III to Category I as well as the reports of other advisory panels. On the basis of this information FDA has tentatively concluded that povidone-iodine should be classified in Category I for use as a first aid antiseptic.

The Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products, in its report published October 13, 1983, stated that "microbiocidal effectiveness of povidone-iodine has been clearly demonstrated by in vitro studies against a variety of pathologic bacteria, fungi, and protozoan organisms" and "in clinical studies, povidone-iodine has been shown to disinfect skin and mucous membrane" (48 FR 46694 at 46705). That Panel classified povidone-iodine diluted to 0.15 to 0.30 percent for use as a douche as Category I for the "relief of minor irritation of the vagina" but reserved directions for use of full-strength solution for professional uses.

The Antimicrobial II Panel reviewed povidone-iodine as a topical antifungal ingredient. In its evaluation, the Panel relied on new safety data as well as the recommendations of the Antimicrobial I Panel in the **Federal Register** published September 13, 1974 (39 FR 33103 at 33129). The Antimicrobial II Panel's recommendations on antifungal use of povidone-iodine were published in the March 23, 1982 **Federal Register** (47 FR 12480 at 12545) as an advance notice of proposed rulemaking. That Panel concluded that 10 percent povidone-iodine was safe for OTC topical antifungal use in the treatment of athlete's foot, jock itch, and ringworm.

The safety aspects of povidone-iodine as a topical first aid antiseptic for consumer use in the home environment (short-term use over limited areas of the skin) are essentially the same as those described by the Antimicrobial II Panel for topical antifungal ingredients. The agency concurs with and adopts the Antimicrobial II Panel's safety evaluation of povidone-iodine. Povidone-iodine is being proposed as generally recognized as safe as an OTC topical first aid antiseptic ingredient in this amended tentative final monograph. (See comments 41 and 42 for additional safety discussions. See comment 39 for effectiveness discussion.)

Reference

(1) Comments No. C00104, C00108, C00111, C00112, C00113, C00128, C00132, and C00133, Docket No. 75N–0183, Dockets Management Branch.

39. Several comments requested that the tentative final monograph specify the lowest potency concentration of available iodine that marketed preparations be allowed to reach before

being considered ineffective and, thus, adulterated or misbranded (Refs. 1 to 4). One comment (Ref. 2) asserted that "many noncompendial povidone-iodine preparations do not specify the labeled amount of iodine, and there is wide variation in their potency. This has created confusion in the market and may put consumers at risk." The comment requested "that those preparations which are placed in Category I contain in the respective use monograph a lower potency limit, irrespective of the original concentration, since this lower limit would still be effective." Another comment (Ref. 3) suggested that the monograph be revised to include povidone-iodine as an antimicrobial bar soap containing not less than 5 percent nor more than 10 percent povidone-iodine U.S.P., equivalent to 0.5 percent and 1.0 percent available iodine. Topical dosage for use as a solution containing not less than 7.5 percent nor more than 10 percent povidone-iodine U.S.P., equivalent to 0.75 percent and 1.0 percent available iodine, was proposed for a health-care personnel hand wash, surgical hand scrub, skin antiseptic, skin wound cleanser, skin wound protectant, or a patient preoperative skin preparation.

One comment (Ref. 4) included data on the rate of release of iodine from povidone-iodine to support effectiveness.

In the previous tentative final monograph, the agency did not discuss or recommend specific concentrations of povidone-iodine for the proposed seven classes of preparations (i.e., antimicrobial soap, health-care personnel handwash, surgical hand scrub, skin antiseptic, skin wound cleanser, skin wound protectant, and patient preoperative skin preparation) (43 FR 1210 at 1235). However, the agency stated that "the question of iodine release from the complexed molecule, including rate of release and binding to other materials, as well as the influence of the release rate on effectiveness, must be resolved" (43 FR 1236).

Subsequently, the agency has reviewed chemical data and in vivo and in vitro biological data that support the effectiveness of povidone-iodine (Refs. 1 through 4). The biological data show that dilutions from marketed 5 percent povidone-iodine and marketed 7.5 to 10 percent povidone-iodine significantly reduced the number of test bacteria within 1 minute (Refs. 1 and 2). According to references that were submitted in connection with another rulemaking, povidone-iodine solution at concentrations of 1 to 10 percent contains over 99 percent complexed iodine (Ref. 5). Based on an iodine-starch reaction as a biological model, it has been shown that any iodine that is removed from the complex would be replaced within less than 25 milliseconds (Ref. 6). The agency's detailed evaluation is on display in the Dockets Management Branch (Ref. 7).

The data show that as the already released iodine interacts chemically with the microbes, more iodine is rapidly released from the povidone-iodine. Consequently, the availability of the iodine is not a problem. Furthermore, povidone-iodine manufactured in accordance with current good manufacturing practices (21 CFR Part 211) should not present problems. Based on the available data, povidone-iodine at 5 to 10 percent concentrations is being classified as Category I for first aid antiseptic use.

Other uses for povidone-iodine will be addressed separately in the segment of this rulemaking dealing with uses other than first aid in a future issue of the **Federal Register.**

References

(1) Comment No. C00104, Docket No. 75N-0183, Dockets Management Branch.

(2) Comment No. C00123, Docket No. 75N-0183, Dockets Management Branch.

(3) Comment No. C00108, Docket No. 75N-0183, Dockets Management Branch.

(4) Comment No. C00111, Docket No. 75N-0183, Dockets Management Branch.

(5) Schenck, H.U., et al., "Structure of Povidone-Iodine," *in* "Current Chemotherapy and Infectious Disease," Volume I, American Society for Microbiology, Washington, pp. 477–478, 1980.

(6) Ditter, W., D. Horn, and E. Luedekke, "Thermodynamic and Kinetic Examinations Concerning the Complex Binding State and the Rate of Liberation of Iodine from Aqueous Iodine-PVP-Solutions," included in Comment No. C00012, Docket No. 81N-0014, Dockets Management Branch.

(7) Letter from W. E. Gilbertson, FDA, to L. Blecher, GAF Corp., October 5, 1983, Coded LET004, Docket No. 81N-0114, Dockets Management Branch.

40. Several comments objected to FDA's requiring expiration dates (not to exceed 2 years after manufacture) for all products containing an iodophor active ingredient (43 FR 1210 at 1235). The comments stated that stability varies among different iodophor products, with some products falling short of, and others far exceeding, this time period. The comments argued that data derived from a particular formulation are not applicable to other iodophor categories or even to formulations containing a common active ingredient because of the nature of the particular formulation, the purity of the active ingredient, other substances used, and the level of manufacturing expertise available.

The comments also pointed out that the fixed 2-year time period is contrary to FDA's policy under the good manufacturing practice regulations, which require that the stability profile of each individual product in its own container-closure system under varying environmental conditions be known and controlled. The comments argued that it is important that expiration dating for iodophor products be supported by each manufacturer, with well-defined test data, for the stability term that is proposed for a particular formulation and that such support data should include studies conducted under conditions of actual use demonstrating that the formulation is stable for the period claimed.

The agency agrees with the comments. At the time the agency proposed expiration dates, the agency was concerned with the lack of stability data submitted for the several iodophor preparations. However, current good manufacturing practice regulations (21 CFR parts 210 and 211) require a testing program to assess the stability of finished products and to determine appropriate storage conditions and an expiration date. Under § 211.137, drug products must bear an expiration date supported by reliable stability data. The agency has proposed an exemption from this requirement for human OTC products that do not bear dosage limitations if appropriate data show that the products are stable for at least 3 years. (See § 211.137(g).) Because of these current good manufacturing practice regulations, the agency concludes it is not necessary to include specific expiration dating periods for dosage forms of povidone-iodine or other iodophors in the amended tentative final monograph. Therefore, the previously proposed 2-year expiration date for iodophors has been eliminated.

41. Several comments submitted data from published and unpublished studies to show that povidone-iodine does not alter thyroid function (Refs. 1 through 12). These data were submitted in response to FDA's request for controlled research to show the conditions of use under which thyroid function would, or would not, be altered (43 FR 1210 at 1235). The comments stated that although the data show that the amount of total serum iodine, or iodide, is increased after povidone-iodine is used topically, there is no significant alteration of the level of thyroid hormone measured by RT_3U, T_3, and T_4 radioimmunoassays.

One comment pointed out that, as part of the ongoing review of food additives, FDA issued a final order on March 31, 1978 (43 FR 11699) (21 CFR 184.1634) confirming that potassium iodide, a salt of iodine, is generally recognized as safe. The comment also pointed out that, in a separate rulemaking procedure for OTC vitamin and mineral drug products (44 FR 16126 at 16181), the Advisory Review Panel on OTC Vitamin, Mineral, and Hematinic Drug Products discussed the safety of iodine and advised that the thyroid can safely absorb up to 2 milligrams of iodine without metabolizing it. This absorption prevents the accumulation of iodine that would inhibit thyroid hormone synthesis. The comment added that the administrative record for the antimicrobial monograph contains adequate data to show that topically applied iodine is virtually not absorbed.

The agency has reviewed the data submitted (Refs. 1 through 12) and agrees with the comments that thyroid dysfunction does not occur from the topical use of povidone-iodine. Plasma iodine levels may be elevated following the topical use of povidone-iodine; however, the thyroid adapts to the iodine elevation, and the iodine is readily excreted by the kidney without evidence of thyroid dysfunction. During a study of the effects of surgical scrubbing with povidone-iodine for 2 weeks, it was concluded that some absorption of iodine did occur when povidone-iodine was used topically (Ref. 12). The serum iodine concentration was elevated, but not protein-bound iodine, T_4, T_3, or TSH. However, the level of serum iodine returned to normal when povidone-iodine use was discontinued. In addition, studies following the application of povidone-iodine to the mucous membranes (vagina) and intact and damaged skin in humans and animals reported protein-bound iodine elevations, but no alterations in thyroid function (Refs. 4, 7, 9, and 10). Therefore, the agency believes that topically applied povidone-iodine does not cause thyroid dysfunction and is safe for OTC use.

References

(1) Alden, E.R., et al., "Effect of Prenatal Povidone-Iodine Perineal Antisepsis on Serum Protein-Bound Iodine," Obstetrics and Gynecology, 35:253–254, 1970.

(2) Garnes, A.L., et al., "Clinical Evaluation of Povidone-Iodine Aerosol Spray in Surgical Practice," American Journal of Surgery, 97:49–53, 1959.

(3) Goldman, M., and D. Landry, "The Effect of Povidone-Iodine on Thyroid Function in Rats," Toxicology and Applied Pharmacology, 35:341–346, 1976.

(4) Gortz, G., "Povidone-Iodine (Mundidone)—Alternative to Topical Antibiotics: Effects and Side Effects in Wound Treatment," 10th International Congress of Chemotherapy, Zurich, 1977.

(5) Higgins, H.P., et al., "The Effect of Povidone-Iodine (Betadine) on Serum Protein-Bound Iodine, When Used as a Surgical Preparation on Intact Skin," The Canadian Medical Association Journal, 90:1298–1300, 1964.

(6) Kearns, J.E., "The Effect of New Iodophors on Protein-Bound Iodine and Butinol Extractable Iodine in Humans," American Journal of Surgery, 109:457–459, 1965.

(7) King, I.R., and A.W. Diddle, "Protein-Bound Iodine and T_4 Tests After Vaginal Application of Povidone-Iodine," American Journal of Obstetrics and Gynecology, 108:1175–1177, 1970.

(8) Lavelle, K.J., et al., "Iodine Absorption in Burn Patients Treated Topically with Povidone-Iodine," Clinical Pharmacology and Therapeutics, 17:355–362, 1975.

(9) Meissner, K., et al., "Povidone-Iodine Versus Antibiotic Application in Prophylaxis and Treatment of Peritonitis: Effects on Thyroid Function," 10th International Congress of Chemotherapy, Zurich, 1977.

(10) Quagliana, J.M., "Effect of Topical Povidone-Iodine (Betadine) on Serum Protein-Bound Iodine," Journal of Clinical Endocrinology and Metabolism. 23:395–397, 1963.

(11) Renk, E., et al., "The Influence of Povidone-Iodine (Mundidone) on the PBI and BEI Serum Levels in Burn and Peritonitis Therapy," 10th International Congress of Chemotherapy, Zurich, 1977.

(12) Ingbar, S.H., "Studies of the Effects of Surgical Scrubbing with PVP–I," unpublished study included in Comment No. C0032, Docket No. 75N–0183, Dockets Management Branch.

42. Several comments objected to the Commissioner's statement in the antimicrobial tentative final monograph that data presented to the Panel suggested that nonsurfactant iodophor products (povidone-iodine) delay the rate of wound healing (43 FR 1210 at 1235). One comment submitted new data to show that povidoneiodine has no adverse effect on wound healing in animals or humans (Refs. 1 through 13). Another comment stated that povidoneiodine may, in fact, aid wound healing.

The agency has reviewed the new data submitted by the comments and agrees that povidone-iodine does not delay wound healing. Controlled studies on wound healing were conducted in animals and humans and involved various types of dermal wounds and several antiseptics, including povidone-iodine. Both superficial and deeper wounds were studied with a contralateral control, and clinical evaluation was also done on patients receiving split-skin grafts. Results showed that there were no statistically significant differences in mean healing times between any of the treatment groups and their saline controls. In addition, microscopic analysis showed no differences in wound healing in the groups studied. These pathological and histological studies did not indicate any deleterious effect of povidone-iodine on wound healing. However, there was also no evidence demonstrating that povidone-iodine might aid wound healing.

References

(1) Paster, Z., "A Study of the Effect of Polydine on Wound Healing," Israel Institute for Biological Research, 1977, unpublished study, EXT012, Docket No. 75N–0183, Dockets Management Branch.

(2) Gruber, R.P., L. Vistnes, and R. Pardoe, "The Effect of Commonly Used Antiseptics on Wound Healing," Plastic and Reconstructive Surgery, 55:472–476, 1975.

(3) Gilmore, O.J.A., "A Reappraisal of the Use of Antiseptics in Surgical Practice," Annals of the Royal College of Surgeons of England, 59:93–103, 1977.

(4) Gilmore, O.J.A., C. Reid, and A. Strokon, "A Study of the Effect of Povidone-Iodine on Wound Healing," Postgraduate Medical Journal, 53:122–125, 1977.

(5) Sindelar, W.F., and G.R. Mason, "Irrigation of Subcutaneous Tissue with Povidone-Iodine Solution for Prevention of Surgical Wound Infections," Surgery Gynecology and Obstetrics, 148:227–231, 1979.

(6) Gilmore, O.J.A., "Prevention of Wound Infection," Lancet, 1:1134, 1973.

(7) Gilmore, O.J.A., and T.D.M. Martin, "Aetiology and Prevention of Wound Infection in Appendectomy," British Journal of Surgery, 61:281–287, 1974.

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(9) Gilmore, O.J.A., and P.J. Sanderson, "Prophylactic Interparietal Povidone-Iodine in Abdominal Surgery," British Journal of Surgery, 62:792–799, 1975.

(10) Gilmore, O.J.A., "Intraperitoneal Povidone-Iodine," Lancet. 2:37–38, 1977.

(11) Morgan, W.J., "Povidone-Iodine Spray for Wounds Sutured in the Accident Department," Lancet, 1:769, 1978.

(12) Gilmore, O. J. A., et al., "Prophylactic Intraperitoneal Povidone-Iodine in Alimentary Tract Surgery," American Journal of Surgery, 35:156–159, 1978.

(13) Gilmore, O. J. A., "Experimental Treatment of Peritonitis and Peritoneal Adhesions with Antiseptics," in "Proceedings of the World Congress on Antiseptics," Limburg/Lahm, Germany, pp. 117–119, 1976.

43. Several comments requested clarification of contradictory statements concerning the compatibility of iodophors in antimicrobial soaps. The agency agreed to delete the statement of incompatibility of povidone-iodine in soap formulation (43 FR 1210 at 1221; comment 70), but then at 43 FR 1236 the agency stated that it was unaware of any data to show that iodophors can be

formulated into antimicrobial soaps. Another comment pointed out that the agency's conclusion at 43 FR 1236 was inconsistent with the list of Category III active ingredients at 43 FR 1229. One comment also requested that poloxamer-iodine complex be deleted from the Category II list for antimicrobial soaps at 43 FR 1227 because there are no stability differences between povidone-iodine and poloxamer-iodine complexes. The comment pointed out that both complexes are currently being marketed as stable products in synthetic soap formulations and argued, therefore, that poloxamer-iodine complex should be made Category III, as was povidone-iodine complex.

The statement regarding incompatibility of iodophors, such as povidone-iodine, that appeared at 43 FR 1236 was in error. The response to comment 70 (43 FR 1221) was correct in stating that povidone-iodine can be formulated in soaps without incompatibility problems. In addition, the list of Category III active ingredients at 43 FR 1229 correctly listed povidone-iodine as a Category III antimicrobial soap. The agency recognizes that both povidone-iodine and poloxamer-iodine complexes can be formulated in soaps without encountering stability problems and will address soap formulations of both complexes in a future issue of the **Federal Register**. (See comment 19.)

J. Comments on Quaternary Ammonium Compounds (quats)

44. One comment requested that benzalkonium chloride be placed in Category I as a skin antiseptic, a patient preoperative skin preparation, and a skin wound protectant, in addition to its present Category I classification as a skin wound cleanser. In support of its request, the comment cited several surgery textbooks and other references that recommend use of benzalkonium chloride at concentrations ranging from 1:750 to 1:5,000 as a preoperative skin preparation, surgical scrub, skin antiseptic for venipuncture, and in urinary tract procedures, especially in catheterized patients (Ref. 1). The comment also submitted 2 studies on a product containing benzalkonium chloride at a concentration of 1:1,000: (1) an in vitro study to demonstrate that this product formulation acts as a physical chemical barrier against contamination by microorganisms, and (2) a study on induced wounds on the arms of 10 healthy subjects to present evidence that this product is nonirritating and neither delays healing nor favors the growth of microorganisms (Ref. 2).

In the previous tentative final monograph, a 1:750 (0.13 percent) use concentration of benzalkonium chloride was proposed as a Category I "skin wound cleanser" (43 FR 1220 at 1236 to 1237). However, this concentration of benzalkonium chloride was categorized as Category III for other uses requested by the comment, i.e., "skin antiseptic," "skin wound protectant," and "patient preoperative skin preparation." The agency stated that it was "not seriously concerned with the safety of 'quats' for 'first-aid' uses, i.e., in skin wound cleansers, skin wound protectants, and skin antiseptics" (43 FR 1236). The agency also stated that "before 'quats' in general can be finally classified for such uses, the following minor issues must be resolved: delay of skin wound repair, contact dermatitis, and sensitivity to 'quats' " (43 FR 1236). The agency limited the use concentration to not greater than 1:750 and advised that data are needed to establish the minimum and maximum concentrations to be included in the monograph. (See comment 53, 43 FR 1219, and 43 FR 1236 to 1237.)

In this amended tentative final monograph for first aid antiseptic drug products, the agency is combining the former categories "skin wound cleaner," "skin wound protectant," and "skin antiseptic" into a new category "first aid antiseptic." (See comment 13.) The other uses for benzalkonium chloride requested by the comment, e.g., "patient preoperative skin preparation" will be addressed in the segment of this rulemaking dealing with uses other than first aid in a future issue of the **Federal Register**.

The agency has evaluated the scientific review of published articles (Ref. 1), as well as data from safety and effectiveness studies on a product containing benzalkonium chloride (Ref. 2). In the studies of the benzalkonium chloride product (1:1000 (0.10 percent)), uniform superficial wounds were made by the ammonium hydroxide blister method on the forearms of each of 10 human test subjects. Tests wounds were treated three times daily for 3 days with benzalkonium chloride and occluded. The control site was untreated and occluded. Quantitative evaluations of resident skin bacteria recovered from test wound and control wound sites demonstrated that benzalkonium chloride significantly reduced the resident bacteria (i.e., 1 $\log_{10}$). In addition, the study showed that although the treated wounds showed a greater degree of erythema than the untreated wounds on observation days 3 and 5, no other significant differences were observed for crust/scab formation, erythema, or epithelization. The agency believes that these data show that benzalkonium chloride is nonirritating and does not interfere with healing of minor wounds.

Based on the new data, the agency concludes that the safe and effective range for benzalkonium chloride has been established between 0.1 percent to 0.13 percent. Because the concerns that the agency raised in the previous tentative final monograph have now been satisfactorily resolved, the agency is including benzalkonium chloride (1:1000, 0.1 percent to 1:750, 0.13 percent) in this tentative final monograph for first aid antiseptic drug products.

References

(1) "Benzalkonium chloride (Zephiran)," unpublished report submitted by Sterling Drug, Inc., Comment No. C00116, Docket No. 75N-0183, Dockets Management Branch.

(2) Unpublished Clinical Wound Healing Studies on Medi-Quik® submitted by Sterling Drug, Inc., Comment No. SUP013, Docket No. 75N-0183, Dockets Management Branch.

45. One comment objected to the 1:750 use concentration limit established for quaternary ammonium compounds in proposed § 333.40(a). The comment submitted safety and efficacy data for a product with a 1:200 concentration of methylbenzethonium chloride, a quaternary ammonium compound. The comment stated that these studies, as well as previously submitted data and a long history of marketing use for this product, demonstrate that this ingredient is safe for consumer use at this concentration. The comment contended that the 1:750 use concentration limit selected by FDA is completely arbitrary and requested that a Category I skin wound cleanser classification be given to this 1:200 concentration of methylbenzethonium chloride.

As discussed in comment 13, skin wound cleansers have been incorporated into a broader group of antimicrobial containing drug products that are designated as first aid antiseptics in this tentative final monograph. The agency has reviewed several reports previously reviewed by the Panel and new material submitted since the Panel report was published, including the data submitted with this comment in the context of this new category. Based on a review of these data, the agency concludes that the 1:200 (0.5 percent) concentration of methylbenzethonium chloride is safe and effective for first aid use on minor cuts, scrapes, and burns.

Apparently, in its original evaluation of these data on methylbenzethonium chloride, the Panel overlooked the 1:200 concentration and referred only to the usual marketed 1:750 concentration of benzalkonium chloride (0.13 percent) as the standard for all quaternary ammonium compounds. The data show that a 0.5-percent concentration of methylbenzethonium chloride is safe and nonirritating. Human studies by Killian (Ref. 1) and by Withers and Hale (Ref. 2) utilizing 0.5 percent methylbenzethonium chloride indicated that the product did not show any significant primary skin irritation, skin fatigue, or sensitization. A study by Vignec (Ref. 3) provided further support that the drug is safe and nonirritating. Vignec used 0.5 percent methylbenzethonium chloride solution full strength on 138 infants suffering from diaper irritation, minor skin conditions, and excoriation and concluded that the drug was safe and nonirritating. The fact that the solution of methylbenzethonium chloride was used under the occlusion of a diaper without evidence of irritation strongly suggests the safety of this concentration.

Maibach (Ref. 4) reported that, even after a 21-day application of 0.5 percent methylbenzethonium chloride under occlusion, minimal irritation was observed. In this study, a 2- by 2-centimeter patch of nonwoven fabric impregnated with 0.2 mL of methylbenzethonium chloride solution was applied to each subject's back and occluded with tape. The patch was removed every 24 hours. After the test site was read, a freshly medicated patch was applied to the same area. The cumulative irritation index score for the 0.5 percent methylbenzethonium chloride preparation was 8.19 and 5.50 out of a possible score of 84. A second study by Maibach (Ref. 5) on 200 subjects used the standard Draize human sensitization test. The investigator concluded that there was no evidence of contact sensitization to the product. Therefore, the agency concludes that a concentration range of 1:750 (0.13 percent) to 1:200 (0.5 percent) of methylbenzethonium chloride is safe and nonirritating as a first aid antiseptic.

The agency's detailed comments and evaluation of the data and the references are on file in the Dockets Management Branch (Ref. 6).

References

(1) Killian, J. A., "Summary of Local Irritation Actions on Skin and of Sensitizing Properties of Bactine," Section II–A, unpublished report to Miles Laboratories, Inc., 1949, OTC Vol. 020088.

(2) Withers, O. R., and R. Hale, "Skin Tests to Bactine on Hypersensitive Patients," unpublished report to Miles Laboratories, Inc., 1951, OTC Vol. 020088.

(3) Vignec, A. J., "Treatment of Diaper Rash," unpublished report to Miles Laboratories, Inc., 1952, OTC Vol. 020088.

(4) Maibach, H. I., "21-Day Cumulative Irritancy Assay," unpublished report, Miles Medical Department Study No. 2213, 1977, Exhibit 6 of SUP014, Docket No. 75N–0183, Dockets Management Branch.

(5) Maibach, H. I., "Modified Draize Human Sensitization—200 Subjects," unpublished report, Miles Medical Department Study No. 2226, 1978, Exhibit 8 of SUP014, Docket No. 75N–0183, Dockets Management Branch.

(6) Letter from W. E. Gilbertson, FDA, to E. B. Peel, Miles Laboratories, Inc., coded LET 038, Docket No. 75N–0183, Dockets Management Branch.

K. Comment on Tribromsalan

46. One comment stated that tribromsalan in its commercially pure form is not a photosensitizer and submitted an unpublished study to support its contention (Ref. 1). In the study the test agent was applied to 25 subjects for 24 hours, followed by exposure to three Minimal Erythema Doses of solar-simulated radiation twice weekly for 3 weeks. The subjects were challenged 10 to 14 days after the last exposure, and the reactions were evaluated 48 and 72 hours later. The study results demonstrated that pure tribromsalan did not cause photocontact allergy, whereas tribromsalan containing 45 percent dibromsalan did. The investigators speculated that the photosensitizing potential attributed to tribromsalan is caused by the presence of dibrominated contaminants.

In addition, the comment included a statement from an expert who had testified before the Panel. This expert had maintained that photosensitization attributable to tribromsalan had not occurred recently and that any earlier cases attributed to tribromsalan were probably due to cross-reactions in patients sensitized to ingredients such as dibromsalan, bithionol, and tetrachlorosalicylanilide or, less likely, hexachlorophene or dichlorophen. The comment requested that tribromsalan be removed from Category II status.

In the **Federal Register** of October 30, 1975 (40 FR 50527), FDA issued a final regulation (21 CFR 310.508) declaring any drug product containing certain halogenated salicylanilides (including tribromsalan) to be a new drug, stating that these ingredients are not generally recognized as safe and effective for use as active or inactive ingredients in any drug product. The study submitted with the comment does not contain sufficient new information to allow the agency to consider tribromsalan generally recognized as safe and effective for OTC drug use. The submitted study, which has since been published (Ref. 2), showed that 2 of the 25 subjects became photosensitized with the sample of tribromsalan containing 45 percent dibromsalan, whereas no subjects had a reaction to the more purified sample of tribromsalan. One of the two subjects who was photosensitized to the tribromsalan that contained dibromsalan developed cross-reactions to the purer sample of tribromsalan. Five subjects who were sensitized by tetrachlorosalicylanilide also showed cross-reactivity to the purer sample of tribromsalan.

When the regulation was published in 1975, the agency recognized that manufacturing limitations for tribromsalan used in earlier formulations resulted in contamination with higher concentrations of more potent photosensitizing chemical impurities, such as dibromsalan and metabromsalan. The agency also noted that the level of impurities was reduced with improved manufacturing techniques and that tribromsalan sensitization was declining, but had not disappeared. In addition to the problem of photosensitization, the agency was concerned about the lack of toxicological data adequate to establish a safe level for use. Another concern was the adverse benefit-to-risk ratio. (See 40 FR 50527 at 50528 and 50530.) In the absence of adequate data to answer these concerns, the provisions of the regulation in § 310.508 for tribromsalan remain in effect. A new drug application containing appropriate toxicological and manufacturing controls information may be submitted to obtain marketing approval for any product containing tribromsalan.

References

(1) Kaidbey, K. H., and Kligman, A. M., "The Photomaximization Test for Identifying Photoallergic Contact Sensitizers," unpublished study, Comment No. C00095, Docket No. 75N–0183, Dockets Management Branch.

(2) Kaidbey, K. H., and Kligman, A. M., "The Photomaximization Test for Identifying Photoallergic Contact Sensitizers," Contact Dermatitis, 6:161–169, 1980.

L. Comments on Triclocarban

47. Several comments requested Category I status for triclocarban as an active ingredient in antimicrobial soaps and presented new safety data. These data included information to elucidate the metabolic pathways and the pharmacokinetics of triclocarban, short-term toxicity data in animals to determine the target organ for toxicity

and the effect and no-effect levels of use (Ref. 1), long-term toxicity data in animals (Ref. 2), and metabolism data in neonate monkeys (Ref. 3). The comments argued that the data confirmed historical experience showing that triclocarban can be safely used in soaps by infants and adults.

The agency has evaluated data and information submitted by the comments and advised a manufacturer that the study entitled "Twenty-Four Month Dietary Toxicity/Carcinogenicity Study of TCC in Rats" (Ref. 2) served to resolve the agency's safety concern regarding blood levels, target organ toxicity, and no effect levels (43 FR 1210 at 1233) and that triclocarban can be recognized as safe for OTC daily topical use in a concentration of 1.5 percent (Ref. 4). However, as stated in comments 10 and 26, antimicrobial soaps making only cosmetic claims are no longer being considered in this rulemaking.

In the previous tentative final monograph, triclocarban (1.5 percent) was categorized in Category III as a skin wound cleanser, and in Category II as a skin antiseptic and skin wound protectant. However, as discussed in comment 13, the agency is no longer using the product category designations of skin antiseptics, skin wound protectants, and skin wound cleansers. Instead, those product categories have been combined into a first aid antiseptic category. The agency has reassessed data that were discussed in the Panel's report (Refs. 1 and 3, 39 FR 33103 at 33125) in light of the first aid antiseptic category, and is proposing a Category III classification for effectiveness for triclocarban (1.5 percent) not in soap forms for use as a first aid antiseptic.

References

(1) Comments No. SUP018, C00099, C00115, and CP0002, Docket No. 75N–0183, Dockets Management Branch.

(2) Comments No. SUP041 and CP0004, Docket No. 75N–0183, Dockets Management Branch.

(3) Comments No. MM0005 and LET047, Docket No. 75N–0183, Dockets Management Branch.

(4) Letter from W. E. Gilbertson, FDA, to G. Roush, Jr., Monsanto Co., coded LET032, Docket No. 75N–0183, Dockets Management Branch.

M. Comments on Triclosan

48. A number of comments submitted data and information from microbiological, mutagenicity, metabolism, cross-sensitization, photosensitization, and drug experience studies on triclosan (Ref. 1). The comments stated that the data and information show that triclosan (up to 1.0 percent) is safe and effective and that triclosan should be placed in Category I for use in the categories that were defined in the previous tentative final monograph, i.e., skin antiseptic, skin wound cleanser, skin wound protectant, antimicrobial soap, health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. In addition, one comment submitted information on triclosan (0.1 percent) for the treatment of diaper rash and on triclosan (0.1 percent) combined with benzocaine for the treatment of sunburn (Ref. 2).

One comment from the manufacturer of triclosan objected to the agency's expressed concern, as stated in the tentative final monograph (43 FR 1210 at 1231 and 1233), that there is proliferation of products containing triclosan marketed to the American consumer (Ref. 3). Arguing that the agency's concerns were without factual basis, the comment submitted sales data, held confidential under 21 CFR 10.20(j)(2)(i)(*d*), showing that overall sales of triclosan in the United States have in fact decreased from 1973 to 1977 and that sales for use in bar soaps and deodorants have also declined from 1973 to 1977. The comment pointed out that it has exclusive United States patent rights for triclosan and that no license has been, or will be, granted under these patents. The comment added that to the best of its knowledge triclosan is not used in infant clothing, a use mentioned in the tentative final monograph (43 FR 1231). The comment stated that if triclosan is placed in Cateqory I for use in antimicrobial soaps, it would limit sales of triclosan to OTC use in antimicrobial and deodorant soaps, underarm deodorants, and registered Environmental Protection Agency (EPA) pesticide products. In the future, sales might be extended to include approved new drug applications. The comment also pointed out that the statement at 43 FR 1233 about the EPA's Office of Special Pesticide Review preparing a report on the proliferation of triclosan-containing products is in error, and that the erroneous statement apparently resulted from a miscommunication between FDA and EPA staff. The comment concluded that the concerns about proliferation raised by the agency in the tentative final monograph should not prevent triclosan from being placed in Category I.

Another comment from the manufacturer of triclosan submitted validation reports and raw data from a 2-year chronic oral toxicity study in rats, and carcinogenicity and reproduction studies conducted in mice, rats, rabbits, and monkeys by Industrial Bio-Test Laboratories (IBT) (Refs. 4, 5, and 6) and asserted that its validation of the studies shows that triclosan is safe.

Several comments objected to the agency's restriction that antimicrobial soaps containing triclosan can only be formulated in a bar soap to be used with water (43 FR 1210 at 1229) (Ref. 1). The comments argued that such a restriction was not applied to the other Category III uses of triclosan, i.e., skin antiseptic, skin wound cleanser, and skin wound protectant, and that such a restriction was not recommended by the Panel in the advance notice of proposed rulemaking. The comments suggested that the footnote under "antimicrobial soaps" limiting triclosan to bar soap was probably intended to apply to cloflucarban, which, like triclocarban, is known for its "physical and/or chemical incompatibility."

With regard to safety, the agency evaluated the validation reports to support long-term use of the ingredient (Refs. 4, 5, and 6) and advised the manufacturer of triclosan that the IBT studies were invalid because of numerous problems. The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Ref. 7).

The manufacturer subsequently stated its intent to no longer rely on the 2-year chronic oral toxicity IBT study (Ref. 8), and submitted a final report from a new 2-year chronic oral toxicity study in rats (Ref. 9). Pending completion of the agency's evaluation of this new 2-year study, triclosan remains classified in Category III for safety for long-term use.

The agency has evaluated other data and information (Ref. 1) and advised the same manufacturer that these studies resolved the agency's safety concerns for short-term use of triclosan when used in concentrations up to 1.0 percent, but that additional effectiveness data were needed before the ingredient could be placed in Category I. The agency's detailed comments are on file in the Dockets Management Branch (Ref. 10). In a response to the agency, the manufacturer of triclosan requested further guidance, included effectiveness data from in vivo studies for chronic uses (i.e., antimicrobial soap, health care personnel handwash, and surgical hand scrub), and requested that in future rulemaking proceedings, triclosan (being bacteriostatic and not bacteriocidal) either be excluded from categorization or designated "not applicable" for short-term uses as a patient preoperative skin preparation, skin antiseptic, skin wound cleanser, and skin wound protectant (Ref. 11).

In view of the new category "first aid antiseptic" and the effectiveness criteria in proposed § 333.10 (see comment 57), the agency is tentatively classifying triclosan as Category III for effectiveness as a first aid antiseptic. The use of triclosan as a health care personnel handwash, patient preoperative skin preparation, and surgical hand scrub and safety for chronic use will be addressed in the non-first aid segment of this rulemaking dealing with uses other than first aid in a future issue of the **Federal Register**. The use of triclosan for the treatment of diaper rash was addressed in the **Federal Register** of June 20, 1990 (55 FR 25246 at 25277). The use of triclosan for the treatment of sunburn will be addressed in another OTC drug rulemaking covering drug products for this use.

The agency has communicated further with EPA and has ascertained that there is no specific report on the proliferation of triclosan (Ref. 12). Regarding exclusive patent rights, the agency advises that these are not among the determining criteria to establish general recognition of safety and effectiveness, and therefore cannot be used in the evaluation. However, having reviewed the new data along with the previously submitted data, the agency concludes that there is no proliferation problem with triclosan.

Finally, the agency did not intend to restrict formulations of triclosan to bar soap. The agency has reviewed the Panel's recommendations and the footnotes in the previous tentative final monograph (43 FR 1210 at 1229) and finds that triclosan under "antimicrobial soaps" was erroneously marked with the reference to the footnote "Category III only when formulated in a bar soap to be used with water."

References

(1) Comments No. CP0001, SUP019, SUP023, C00103, C00109, SUP031, SUP039, and C00134, Docket No. 75N–0183, Dockets Management Branch.

(2) Comment No. SUP020, Docket No. 75N–0183, Dockets Management Branch.

(3) Comment No. OB0015, Docket No. 75N–0183, Dockets Management Branch.

(4) "Two Year Chronic Oral Toxicity Study With Fat 80' 023/A in Albino Rats," Comment No. C00109, Volume 1, Appendix E, and Comment No. C00139, Volumes 1 through 8, Docket No. 75N–0183, Dockets Management Branch.

(5) "Eighteen Month Carcinogenicity Study with Fat 80' 023/A in Albino Mice," Comment No. C00109, Volume 3, Appendix I, and Comment No. C00139, Volume 9, Docket No. 75N–0183, Dockets Management Branch.

(6) "Three Phase Reproduction Study Albino Rats and Rabbits, Bacteriostat CH 3565," Comment No. C00134, TAB 7, and Comment No. C00139, Volumes 10 through 11, Docket No. 75N–0183, Dockets Management Branch.

(7) Letter from W. E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET028/ ANS, Docket No. 75N–0183, Dockets Management Branch.

(8) Memorandum of Meeting between FDA Staff and Representatives of Ciba-Geigy Corp., Comment No. MM0007, Docket No. 75N–0183, Dockets Management Branch.

(9) "FAT 80' 023 2-Year Oral Administration in Rats," Volumes XLI, XLII, and XLIII and "Determination of FAT 80' 023 in Blood and Tissue Samples Taken During a Two-Year Chronic Oral Toxicity/ Oncogenicity Study in Albino Rats," Volume XLIV, Comment No. RPT002, Docket No. 75N–0183, Dockets Management Branch.

(10) Letter from W. E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET034, Docket No. 75N–0183, Dockets Management Branch.

(11) Comments No. MM0003 and C00157, Docket No. 75N–0183, Dockets Management Branch.

(12) Letter from A. E. Castillo, EPA, to W. E. Gilbertson, FDA, coded LET033, Docket No. 75N–0183, Dockets Management Branch.

N. Comments on Drug Combinations

49. Several comments objected to the agency's decision not to allow combinations of an antimicrobial ingredient and a nonantimicrobial active ingredient or ingredients. (See comment 44, 43 FR 1210 at 1217.) The comments requested that the monograph provide for combinations of an antimicrobial active ingredient with a nonantimicrobial active ingredient or ingredients provided that the combinations are "labeled for use solely for the concurrent symptoms indicated for the active ingredients." Some of the comments pointed out that such combinations were submitted to the Panel for review, e.g., a combination of chloroxylenol and petrolatum (39 FR 33103 at 33104). One comment contended that it was contradictory for the agency to reject the chloroxylenol-petrolatum combination and at the same time define a skin wound protectant in § 333.3(h) of the tentative final monograph as a product that provides both a physical and chemical barrier to infection of small, cleansed wounds, in as much as nonantimicrobial ingredients appear to be necessary to provide the physical barrier of a skin wound protectant. One comment specifically requested that the combination of a topical antimicrobial ingredient with a topical anesthetic ingredient be included in the monograph, stating that such a combination has long been recognized as an effective method of treatment. Another comment made a similar request regarding the combination of alcohol and a topical anesthetic ingredient.

The agency agrees with the comments that antimicrobial ingredients (including alcohol) to help prevent infection can be combined appropriately with nonantimicrobial ingredients to provide concurrent relief for symptoms of minor cuts, scrapes, or burns provided the combination product meets the requirements of § 330.10(a)(4)(iv) (21 CFR 330.10(a)(4)(iv)).

In the previous tentative final monograph, the agency stated that no combinations of antimicrobial and nonantimicrobial active ingredients "are known to exist" (43 FR 127). The agency's statement was based on the Panel's recommended criteria for combining antimicrobial and nonantimicrobial active ingredients and the Panel's recommendation that "if a skin antiseptic claim is made it must meet the requirement of the definition of a skin antiseptic" (39 FR 33103 at 33106). In accordance with the Panel's criteria, neither the Panel in its report nor the agency in the tentative final monograph recognized any Category I skin antiseptics; therefore, no Category I combinations of skin antiseptic and nonantimicrobial ingredients existed. However, because this tentative final monograph is proposing a new category for first-aid antiseptics instead of the category of skin antiseptics and because the definitions for these categories are different, the agency reviewed the submissions to the Antimicrobial Panel in light of the new definition and has determined that combinations containing first aid antiseptics with a topical anesthetic or with a skin protectant do exist. The agency has tentatively determined that these combinations provide rational concurrent therapy, have been previously marketed OTC, meet the requirements in § 330.10(a)(4)(iv), and can be generally recognized as safe and effective. Accordingly, the agency is including the combinations mentioned by the comment in this tentative final monograph.

The agency proposed in § 348.50(b)(2) of the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5868) the following indication for local anesthetics: "For the temporary relief of" (select one of the following: "pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following) "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritation.")

The agency proposed in § 347.50(b)(1) of the tentative final monograph for OTC skin protectant drug products (48

FR 6820 at 6832) the following indication for skin protectants: "For the temporary protection of minor cuts, scrapes, burns, and sunburn." These indications are very similar to the indication for first aid antiseptics in § 333.50(b) of this proposed monograph. Nevertheless, it should be noted that first aid antiseptics are classified in Category I for safety based on labeling that they be indicated for use only on small areas of the body for a minor cut, scrape, or burn and that they have a warning not to apply over large areas of the body. Accordingly, those Category I claims for external analgesic drug products or skin protectant drug products that refer to conditions other than minor wounds, and particularly conditions likely to involve large areas of the body (e.g., sunburn), would be Category II for topical antiseptic-anesthetic and antiseptic-skin protectant combination drug products. Accordingly, the agency is proposing the following combinations as Category I in this tentative final monograph:

(1) Any single first aid antiseptic active ingredient identified in § 333.10 may be combined with any single skin protectant active ingredient identified in § 347.10 provided that the product is labeled according to § 333.60.

(2) Any single first aid antiseptic active ingredient identified in § 333.10 may be combined with any single external analgesic active ingredient identified in § 348.10(a) provided the product is labeled according to § 333.60.

The agency is proposing that these combinations bear the general antiseptic labeling indication that appears in § 333.50(b). In addition, the agency is proposing that these combinations can bear the following additional indications:

(1) Antiseptic-external analgesic combination: "First aid for the temporary relief of" (select one of the following: "pain," "discomfort," "pain or discomfort," or "pain and itching") "in minor cuts, scrapes, and burns."

(2) Antiseptic-skin protectant combination: "First aid for the temporary protection of minor cuts, scrapes, and burns."

50. One comment submitted animal, human, and in vitro studies to establish that a combination of 4.7 percent phenol and 10.8 percent camphor (camphorated phenol) in an oil-based vehicle is safe and effective as a first aid product and skin wound protectant (Refs. 1 and 2). (Camphorated phenol is FDA's preferred common name for complexes of camphor and phenol.) The comment stated that this combination was consistent with the Panel's statement that "when camphor is used with phenol in an oil formulation, the concentration of phenol should be no more than 5 percent" (43 FR 1210 at 1238). The comment further stated that "the clathrate complexing of the two ingredients alters the toxicity materially" and that this product has had a long history of safe use with minimal accidental ingestions. The comment concluded that, because of the product's packaging, there is practically no likelihood of mistaking it for mineral oil or castor oil, as has happened with camphorated oil products. The agency has evaluated the reports submitted by the comment (Refs. 1 and 2) and the data submitted to the Antimicrobial I Panel and has determined that camphorated phenol (containing 4.7 percent phenol and 10.8 percent camphor) is safe and effective for use by consumers as a first aid antiseptic.

In a separate rulemaking for OTC external analgesic drug products, the agency categorized the complex (which was described as a combination in that rulemaking) containing camphor and phenol as Category I for short-term use (i.e., 7 days) as an external analgesic, e.g., "for pain and itching of minor cuts and scrapes." The indication for this drug used as an "external analgesic" (48 FR 5852) is similar to the claims in this proposed first aid monograph.

In the external analgesic rulemaking, the agency proposed the following warning for phenol and phenol-containing products: "Do not apply over large areas of the body or bandage" (48 FR 5852 at 5869). This warning is similar to the warning for phenol proposed by the Antimicrobial I Panel (39 FR 33133) and the agency in the previous tentative final monograph (43 FR 1238): "Warning: Do not * * * cover the treated area with a bandage or dressings." There is also an existing required warning in § 369.20 for carbolic acid (phenol) preparations (more than 0.5 percent) for external use: "Warning—Use according to directions. Do not apply to large areas of the body. If applied to fingers or toes, do not bandage." As discussed in comment 25, the agency has included the warning "Do not use in the eyes or apply over large areas of the body," to the general warnings applicable to all first aid antiseptic drug products. Consistent with the external analgesic tentative final monograph and 21 CFR 369.20, the agency is also proposing a separate warning specific for phenol containing products: "Do not bandage."

As discussed in the external analgesic rulemaking, the agency has verified that the amount of free phenol is reduced when camphor and phenol are combined. The Antimicrobial I Panel stated that "when camphor is used with phenol in an oil formulation, the concentration of phenol should be no more than 5 percent" (39 FR 33103 at 33133). In reviewing data on camphor/phenol combinations, the Antimicrobial I Panel concluded that "The presence of camphor also retards the absorption of phenol after topical application. A 1-hour exposure of the rat tail to a 4.8 percent aqueous phenol solution resulted in the absorption of 71 mg of phenol; whereas, the presence of 10.9 percent camphor combined with 4.5 percent phenol resulted in the absorption of only 16 mg phenol * * *" (39 FR 33122).

The agency concluded in the previous tentative final monograph for OTC topical antimicrobial drug products that "the total concentration of phenol in powders and in aqueous, alcoholic or oil formulations be restricted to less than 1.5 percent. When camphor is used with phenol in an oil formulation, the concentration of phenol should be no more than 5 percent" (43 FR 1210 at 1238). The agency agrees with the comment that, based on the data, the antiseptic phenol combined with camphor can be safely used at a higher concentration than phenol used alone. To reduce the irritating potential of phenol when concentrations of 4.7 percent are used, camphor must be present in excess of that concentration. Accordingly, the agency is including camphorated phenol (containing 4.7 percent phenol combined in a complex with 10.8 percent camphor) in a light mineral oil, U.S.P. vehicle in this first aid antiseptic tentative final monograph.

The agency agrees with the comment that camphor/phenol combinations are unlikely to be mistaken for mineral oil or castor oil and that the adverse reaction information supports the safety of the combination.

References

(1) Comment No. SUP013, Docket No. 75N-0183, Dockets Management Branch.

(2) Comment No. C00116, Docket No. 75N-0183, Dockets Management Branch.

51. One comment from a manufacturer of products containing camphorated metacresol disagreed with the Category II classification of formulations containing more than 5 percent phenol or amyltricresols when used with camphor and with the Category III classification of products containing less than 5 percent phenol or amyltricresols when used with camphor (43 FR 1210 at 1238). The comment claimed that "the special safety and effectiveness of these products is based on the existence of a camphor-metacresol complex or one-phase solution, which acts to release

controlled quantities of 'free' metacresol at completely non-toxic levels." The comment stated that a large number and variety of studies had been conducted to demonstrate the safety, effectiveness, and chemical identity of the complex and that, even though the most modern techniques had not been used, the studies should not have been rejected by FDA. The comment submitted new data (Ref. 1) purporting to show that metacresol has a low toxicity compared with other cresols and phenol; that camphorated metacresol is an effective bactericide; and that the antiseptic action of cresols is not due to protein binding and consequently would not encourage continued release of "free" metacresol from the camphorated metacresol complex. Citing the long marketing history of these products, the comment stated that no adverse drug reactions have been reported. The comment argued that this absence of complaints is especially significant because the products are primarily marketed to doctors, nurses, and paramedics for professional use in industrial settings. These professionals are trained to observe and report adverse reactions, treat a limited clientele, and are in close communication with their pharmaceutical suppliers. The comment requested, for the above reasons, that products containing the combination of camphorated metacresol be reclassified into Category I for safety and effectiveness for use as a skin wound cleanser and skin wound protectant without restriction on the metacresol content.

The agency has evaluated the data and concludes that camphorated metacresol limited to a range of camphor 3 to 10.8 percent and metacresol 1 to 3.6 percent in a 3:1 ratio is safe and effective as a first aid antiseptic.

Subsequent to the previous tentative final monograph, the recommendations on camphorated metacresol made by the Advisory Review Panel on OTC Antimicrobial II Drug Products in conjunction with its review of OTC antifungal drug products were published in the Federal Register of March 23, 1982 (47 FR 12480 at 12536). That Panel reviewed cresol, the mixture of ortho, meta, and para cresol, and concluded that "Cresol is structurally and pharmacologically related to phenol and * * * is more active against bacteria than phenol and has a phenol coefficient of 2 to 3. The three chemical isomers of cresol (*m*-cresol, *o*-cresol, *p*-cresol) vary little in bactericidal properties" (47 FR 12536). The agency agrees with these findings.

In a separate rulemaking for OTC external analgesic drug products, the agency regarded metacresol as similar to phenol and categorized camphorated metacresol as Category I for short-term use (i.e., 7 days) as an external analgesic, e.g., for pain and itching of minor cuts and scrapes (48 FR 5852 at 5858). This external analgesic indication is similar to the claims in this proposed first aid monograph. As discussed in the external analgesic rulemaking (48 FR 5858), the agency has determined that metacresol behaves similarly to phenol with respect to bonding with camphor and therefore can be considered a "complex" and categorized as camphorated metacresol.

Based on the available information, which includes recognition of the combination of phenol and camphor as Category I, data showing that metacresol has the same toxicity as phenol or is less toxic, and the new data showing that metacresol bonds to camphor similarly to phenol, the agency has tentatively concluded that camphorated metacresol is Category I when prepared from camphor and metacresol combined in a 3-to-1 ratio not to exceed a concentration of 10.8 percent camphor. Based on a 3-to-1 ratio of camphor to metacresol with a limit of 10.8 percent camphor, the upper limit for metacresol is 3.6 percent. This 3-to-1 ratio results in reduced irritation. The agency is proposing a lower limit of 1 percent metacresol based on information on marketed products submitted by the comment.

In addition, the same warning, "Do not bandage," as discussed in comment 50 with regard to phenol/camphor, will apply to camphorated metacresol.

The comment did not provide sufficient data to establish general recognition of safety of a concentration of metacresol greater than 3.6 percent when this ingredient is combined with camphor. The studies submitted by the comment (Ref. 1) were very limited in scope and were inadequate to demonstrate the safety of higher concentrations. Most of the animal toxicity studies tested only one animal, observed the animal only for a short period of time, and did not include a detailed examination of the animal following drug application. The comment's statements about rate of release of metacresol are unsupported because the comment submitted no information on the quantity of metacresol released under the conditions of use. The comment also did not submit any data to support the safety of concentrations of camphor above 10.8 percent.

The marketing history information submitted in the comment does not provide proof of safety for camphor concentrations above 10.8 percent or metacresol concentrations above 3.6 percent. The safety of camphorated metacresol as a first aid antiseptic above 3.6 percent metacresol and 10.8 percent camphor has not been established.

Therefore, the agency proposes to classify camphorated metacresol (a complex consisting of camphor and metacresol combined in a ratio of 3 parts camphor to 1 part metacresol) at concentrations from 1 to 3.6 percent metacresol and from 3 to 10.8 percent camphor as Category I for use as a first aid antiseptic.

References

(1) Comment No. SUP035, Docket No. 75N-0183, Dockets Management Branch.

(2) Comment No. C00098, Docket No. 75N-0183, Dockets Management Branch.

52. One comment stated that the Panel did not review safety and effectiveness data submitted to it on mercufenol chloride (orthohydroxyphenylmercuric chloride) 0.1 percent and secondary amyltricresols 0.1 percent as single ingredients and in combination for use as a patient preoperative skin preparation, skin antiseptic, and skin wound protectant (Ref. 1). The comment added that the agency did not discuss these ingredients alone or in combination in the previous tentative final monograph.

The comment asserted that secondary amyltricresols, mentioned in the previous tentative final monograph under phenol (43 FR 1210 at 1238), are not equivalent to phenol because of chemical differences and differing antimicrobial properties, formulation concentrations, and patterns of use. The comment requested the agency to make decisions on the safety and effectiveness of this ingredient when used alone, or in combination, as a patient preoperative skin preparation, a skin antiseptic, or a skin wound protectant.

The agency has reviewed the submitted data and finds that they are insufficient to determine the safety and effectiveness of 0.1 percent mercufenol chloride and 0.1 percent secondary amyltricresols either singly or in combination for use as a first aid antiseptic. Another panel, the OTC Miscellaneous External Panel, reviewed data other than that provided in this comment and found mercufenol chloride to be safe for topical use at a 0.056-

percent concentration (47 FR 436 at 441). However, the available data are insufficient to establish the safety of this ingredient at 0.1 percent. Only safety data on animals were submitted by the comment (Ref. 1); in general, these studies were conducted on a very small number of animals, did not detail methodology, and did not adequately describe results (physical conditions of the animals). The submitted in vitro studies also lack sufficient detail to establish the effectiveness of mercufenol chloride.

Secondary amyltricresols are mixtures of isomeric secondary amyltricresols, which are derivatives of phenol, and have pharmacological properties similar to phenol. The agency agrees with the comment that the mixture of secondary amyltricresols is not equivalent to phenol and should be categorized separately from phenol. The submitted safety data included a study by Broom (Ref. 2), who reported that amylmetacresol is relatively nontoxic and less toxic than hexylresorcinol in rats and mice.

No toxicity studies in humans were included in the information provided by the comment. However, in the tentative final monograph for OTC external analgesic drug products, published in the Federal Register of February 8, 1983 (48 FR 5852 at 5856), the agency proposed that metacresol up to a 3.6-percent concentration be considered safe when combined with camphor and that a 3-to-1 ratio of camphor to metacresol reduces the irritating properties of metacresol. Although cresols may cause some irritation when applied to minor wounds, the agency believes that secondary amyltricresols at the concentration requested (0.1 percent) would not present any safety concerns, particularly considering the short-term use of first aid products. The submitted data are, however, inadequate to establish the efficacy of secondary amyltricresols.

Data are also needed to determine the safety and effectiveness of the combination of mercufenol chloride and secondary amyltricresols. Only animal safety data are available, and these studies were limited to determinations of the minimum lethal dose by various routes of administration (Ref. 1). The submitted information on marketing history is not sufficient to provide general recognition of the safety of these ingredients. The data contained isolated reports of the combination of mercufenol chloride and secondary amyltricresols causing occasional skin irritation, such as burning and blistering (Ref. 1), adverse effects that need to be more fully studied.

Most of the effectiveness work on the combination of mercufenol chloride and secondary amyltricresols has been in vitro. The combination is reported to combine the antibacterial activity of the single ingredients, that is, mercufenol chloride, which is primarily active against gram-negative organisms, and secondary amyltricresols, which are primarily active against gram-positive organisms (Ref. 3). One in vivo study on the effectiveness of the combination as a patient preoperative skin preparation showed a substantial reduction in the skin microflora (Ref. 4). However, because neutralizers were not used, bactericidal activity cannot be differentiated from residual bacteriostatic activity. In addition, the effect of the 50-percent alcohol in the alcohol-acetone vehicle was not taken into consideration. Alcohol, 48 to 95 percent, has been classified Category I in this first aid antiseptic rulemaking.

Under the agency's guidelines for OTC drug combination products (Ref. 5), Category I active ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the combination policy in all respects and the combination is on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. Accordingly, both mercufenol chloride and secondary amyltricresols and the combination of these ingredients are placed in Category III. The combination needs further testing of the combined ingredients compared to each individual active ingredient to establish effectiveness of the combination as a topical antiseptic for first aid use.

References

(1) OTC Volume 020093.

(2) Broom, W.A., "A Note on the Toxicity of Amyl-meta-cresol," British Journal of Experimental Pathology, 12:327–331, 1931.

(3) Dunn, C.G., "Germicidal Properties of Phenolic Compounds," Industrial and Engineering Chemistry, 28:609–612, 1936.

(4) Maddock, W.G., and L.K. Georg, "Further Experience with Mercresin," American Journal of Surgery, 45:72–75, 1939.

(5) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

53. One comment submitted data on the safety and effectiveness of triclocarban and triclosan combined in a deodorant bar soap and requested that this antibacterial combination in a bar soap be included in the OTC topical antimicrobial final monograph (Ref. 1). The comment mentioned that these data were submitted prior to the publication of the previous tentative final monograph, but were not addressed in that document.

The data were not addressed in the previous tentative final monograph because they were received too late for inclusion in that document. As discussed in comment 26, deodorant bar soaps for which only cosmetic claims are made are considered cosmetics.

Reference

(1) Comments No. LET003 and SUP029, Docket No. 75N–0183, Dockets Management Branch.

54. One comment submitted data on the safety and effectiveness of a product containing a combination of eucalyptol, menthol, methyl salicylate, thymol, and 26.9 percent alcohol for use as a first aid remedy and topical antiseptic for the treatment of minor cuts and scratches (Ref. 1). Noting that the product is marketed primarily as an antiseptic mouthwash, the comment stated that it is also labeled and indicated for the treatment of minor cuts and scratches. The comment added that the safety of the ingredients and the total formulation had been acknowledged by two different FDA advisory panels, i.e., the Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Panel (Cough-Cold Panel) and the Oral Cavity Panel.

References to antiseptic activity of the individual aromatic oils and their combination in the scientific literature were submitted (Ref. 1). Studies of the individual oils (eucalyptol, menthol, methyl salicylate, and thymol), their vapors, and solutions against a wide variety of gram-positive and gram-negative microorganisms were described in the comment. Phenol coefficients were reported for each of the oils. These coefficients show that each oil is more active than phenol against frequently occurring organisms. For example, the following approximate phenol coefficients have been reported: eucalyptol, 1.8; menthol, 5.1; methyl salicylate, 1.8; and thymol, 27.6 (Ref. 1).

The comment included studies (Ref. 1) to demonstrate that the combination of oils is more effective than each of the individual ingredients and that each of the oils provides a statistically significant contribution to the activity of the product.

Further support for the antiseptic activity of the combination is provided by the in vitro antiseptic activity test proposed by the OTC Oral Cavity Panel. The comment stated that at no time has the product failed to kill all three of the

prescribed microorganisms, *C. albicans*, *Streptococcus mutans*, and *Actinomyces viscosus*, in less than 5 minutes regardless of the test conditions. This includes tests conducted in the presence of saliva, horse serum, or fetal calf serum, each of which may inactivate certain antiseptic agents.

One submitted clinical study compared the antiseptic effect of the combination product, 70 percent ethanol, and water on the skin flora. The study revealed that a 60-second wash of the skin surface with the combination product results in a statistically significant reduction in numbers of surface bacteria. The comment pointed out that there were no significant differences between the combination product and 70 percent ethanol, a widely recognized and recommended antiseptic agent. A gradual recovery of the bacterial count occurs with time, but significantly reduced counts relative to pretreatment values exist 1 and 3 hours postwash after using the combination product and 70 percent ethanol.

Therefore, the comment requested that the agency consider this combination of ingredients to be Category I as a first aid antiseptic in the antimicrobial monograph.

Data and information on the individual essential oils were reviewed by the Oral Cavity Panel, and these ingredients were categorized as Category I for safety. (See the **Federal Register** of May 25, 1982, 47 FR 22760.) The agency affirms that Panel's conclusions that these individual essential oils are generally recognized as safe. The Cough-Cold Panel also reviewed the ingredients, except for methyl salicylate, and classified them in Category I for safety (41 FR 38311 at 38312). Methyl salicylate was classified in Category I for safety by the Topical Analgesic Panel (44 FR 69768); this classification was confirmed by the agency in the tentative final monograph for OTC external analgesic drug products (48 FR 5852).

The comment submitted data from in vitro studies showing that a formulation of 0.063 percent thymol, 0.042 percent menthol, 0.055 percent methyl salicylate, and 0.091 percent eucalyptol in 26.9 percent alcohol reduced the number of bacteria in *S. aureus* cultures 5.2 $\log_{10}$ within 1 minute at 37 °C when assayed at 40 percent of the formulation's recommended use concentration. Furthermore, when formulations lacking thymol, menthol, methyl salicylate, or eucalyptol were diluted and assayed as described above, the numbers of bacteria were reduced 0.6, 2.4, 3.1, and 3.4 $\log_{10}$, respectively, thus demonstrating that each essential oil contributed significantly to the total antimicrobial efficacy of the complete formulation. Because concentrations of alcohol exceeding 25 percent (v/v) are necessary to inactivate *S. aureus* within 1 hour (Ref. 2), concentrations of 10.76 percent (v/v), such as that contained in the diluted formulations assayed, would not be expected to have significant antimicrobial activity when tested as a single active ingredient. However, antiseptics prepared as hydroalcoholic tinctures have been demonstrated to be more efficacious than aqueous preparations even when dilutions of the tincture high enough to rule out the bactericidal action of the alcohol are assayed (Ref. 3). Thus, the addition of co-solvents to an aqueous phase can influence antimicrobial activity by either the inherent toxicity of the co-solvent, or through the effect of the co-solvent on the thermodynamic activity of an antimicrobial agent, or both (Ref. 4).

The comment also submitted data from in vivo studies which compared the antimicrobial efficacy of four treatment regimens: a formulation of the above mentioned essential oils in 26.9 percent alcohol; 70 percent (v/v) alcohol; water; and no treatment. Treatment consisted of wiping the skin surface for 1 minute with a 2"×2" sterile gauze sponge soaked in the treatment solution, or the site was left untreated to serve as the nontreated control. Bacterial samples were taken from the skin surface by a contact plate method once prior to treatment, immediately after treatment and again at 1 and 3 hours later. Results of the immediate post-treatment evaluation when compared with pre-treatment bacterial counts showed that 70 percent alcohol, the combination of essential oils in 26.9 percent alcohol, water, and no treatment reduced the numbers of organisms 1.69, 1.51, 0.43, and 0.03 $\log_{10}$, respectively. Statistically significant residual effects were observed at 1 and 3 hours after treatment with 70 percent alcohol and the combination of essential oils in alcohol, while water produced a significant reduction immediately and at 1 hour post-wash. Differences in antimicrobial efficacy between 70 percent alcohol and the combination of essential oils in alcohol at 0, 1, and 3 hours post-treatment were not statistically significant.

Although this combination product contains more than two active ingredients from the same pharmacological group (i.e., eucalyptol, menthol, methyl salicylate, and thymol), paragraph 3 of the agency's "General Guidelines for OTC Drug Combination Products" (Ref. 5) permits such a combination "* * * if the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose." In addition, although the individual ingredients have not been classified, the ingredients may be evaluated as a combination based on paragraph 5 of the agency's "General Guidelines" (Ref. 5), which states that "in some cases an ingredient may be appropriate for use only in a specific combination or data may be available only to support the use of the ingredient in combination but not as a single ingredient. In such cases the ingredient will be placed in Category I for use only in the permissible combinations and not as a single ingredient."

Based on these guidelines and discussion above, the agency believes that the combination of eucalyptol 0.091 percent, menthol 0.042 percent, methyl salicylate 0.055 percent, and thymol 0.063 percent in alcohol 26.9 percent may appropriately be included in this amended tentative final monograph as Category I for first aid antiseptic use.

References

(1) Comment No. C00135, Docket No. 75N-0183, Dockets Management Branch.

(2) Morton, H.E., "The Relationship of Concentrations and Germicidal Efficacy of Ethyl Alcohol," Annals of The New York Academy of Sciences, 53:191–196, 1950.

(3) Dunn, Cecil, G., "Germicidal Properties of Phenolic Compounds," Industrial and Engineering Chemistry, 28:609–612, 1936.

(4) Kostenbauder, H.B., "Physical Factors Influencing the Activity of Antimicrobial Agents," Disinfection, Sterilization and Preservation, Edited by Seymour S. Block, Lea and Febiger, Philadelphia, p. 913, 1977.

(5) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

55. One comment requested that the agency consider the combination of epinephrine hydrochloride 0.1 percent and methylbenzethonium chloride 0.25 percent for OTC use in the treatment of minor cuts and abrasions. The comment stated that this combination is rational because it contains an antimicrobial agent, methylbenzethonium chloride, to aid in controlling infections and a vasoconstrictor, epinephrine hydrochloride, to help stop the bleeding of a minor wound. The comment added that epinephrine hydrochloride has been marketed in combination products for 35 years; that its safety and efficacy have been confirmed by the Advisory Review Panel on OTC Hemorrhoidal Drug Products (Hemorrhoidal Panel); and that the agency had classified

methylbenzethonium chloride in Category I as a skin wound cleanser in the tentative final monograph for OTC topical antimicrobial products (43 FR 1210 at 1246).

The agency has reviewed the data submitted by the comment (Ref. 1) and concludes that the data are insufficient to establish the safety and effectiveness of a combination of epinephrine hydrochloride 0.1 percent and methylbenzethonium chloride 0.25 percent to treat minor cuts and scrapes.

As discussed in comment 45, the agency considers methylbenzethonium chloride to be safe and effective as a first aid antiseptic at concentrations of 0.13 to 0.5 percent. Although epinephrine has been used for many years as a vasoconstrictor and bronchodilator, its effect on a skin wound in an area of poor circulation, such as an elderly person's finger or toe, needs further study. It has been suggested that epinephrine should not be applied to an area supplied by end arteries, such as the finger, toe, or ear, because of the danger of vascular insufficiency and sloughing (Ref. 2). It should be determined whether vasoconstriction in such a compromised area could induce gangrene.

The agency also finds the submitted data inadequate to determine the effectiveness of this combination. Epinephrine has been used by injection for many years, particularly in local anesthetics to decrease bleeding during surgical procedures, but it has not been as extensively used topically to treat skin wounds. Most of the studies on human skin cited by the comment used either local or intramuscular injections of epinephrine, and not topical applications. No human skin wound studies using epinephrine to stop bleeding were cited by the comment. Further testing of the combination is necessary to determine its effectiveness as a first aid antiseptic for minor cuts and scrapes.

The agency's detailed comments and evaluations on the data and its recommendations for additional studies are on file in the Dockets Management Branch (Ref. 3).

References

(1) Comment No. C00149, Docket No. 75N-0183, Dockets Management Branch.

(2) Denton, J., R.L. Schreiner, and J. Pearson, "Circumcision Complication," Clinical Pediatrics. 17:265-6, 2978.

(3) Letter from W.E. Gilbertson, FDA to K. Johannes, Plough, Inc., coded LET040, Docket No. 75N-0183, Dockets Management Branch.

O. Comments on Testing

56. Several comments requested that the effectiveness requirements for the skin antiseptic drug product category be similar to the requirements for other antimicrobial categories; such as the patient preoperative skin preparation or surgical scrub, for which effectiveness data must show a reduction of the number of bacteria on the skin, and that studies for demonstrating prevention of overt skin infection not be required.

Several comments submitted protocols for determining the in vitro effectiveness of products for general antiseptic use. The lists of microorganisms to be tested varied; but *P. aeruginosa, S. aureus;* and *E. coli* were included in each protocol because they were considered to be the organisms commonly encountered.

One comment asked that efficacy data be reviewed in light of the relevancy of percentage limits of antiseptic to the label claim and that a minimum limit of antiseptic be established for microbiocidal effectiveness. The comment provided experimental data and described a protocol used to determine the quantitative antimicrobial activity of two products of 10 percent povidone-iodine solution. The protocol specified the test organisms for the microbial suspension and the neutralizer to be used and provided for the addition of organic matter (serum) to the culture media in order to determine the minimal inhibitory concentration of the products at different intervals (i.e., zero hour, 15 seconds, 30 seconds, 1 minute, and 5 minutes). Incubation temperature for this in vitro test was 35 °C.

OTC first aid antiseptic drug products are not intended for the treatment of infection or for the prevention of overt infection, but only as an aid in helping to prevent infection of minor cuts, burns, and scrapes. Therefore, the agency finds that studies demonstrating prevention of overt skin infection, which was included in the previous tentative final monograph as part of the definition for a "skin antiseptic," are not necessary for a first aid antiseptic labeled "to help prevent infection in minor cuts, scrapes, and burns."

Demonstrated in vitro antiseptic bactericidal or bacteriostatic action is of predictive value in projecting in vivo efficacy for first aid antiseptics. Based on the comments and the considerations above, the agency has developed effectiveness criteria and procedures for testing final formulations of first aid antiseptic drug products. As recommended by the comments, the organisms *P. aeruginosa. S. aureus,* and *E. Coli* are identified as organisms to be tested. Neutralizers and culture media are discussed in the testing procedures, which are being proposed for inclusion in § 333.70 of the monograph and are described below.

The agency invites specific comment at this time on the testing requirements being proposed in § 333.70. After reviewing any submitted comments or data, the agency may revise the testing procedures prior to establishing a final monograph. The agency also recognizes that the test procedures may need to be revised periodically as newer techniques are developed and proven adequate.

Therefore, the agency is proposing that an OTC first aid antiseptic drug product in a form suitable for topical application meet the standards of the in vitro test included in § 333.70. Because the agency has received data on hydrogen peroxide topical solution, U.S.P., iodine tincture, U.S.P., and iodine topical solution, U.S.P., sufficient to support efficacy for these drug product formulations (see comments 36 and 39), these drug products, when formulated to meet U.S.P. specifications, are exempt from the in vitro testing procedure described in § 333.70.

57. Two comments requested that the agency clarify its position on final formulation testing of antimicrobial drug products because of apparent contradictions between the response to comment 7 (43 FR 1210 at 1211), statements appearing under the testing guidelines at 43 FR 1240, and the response to comment 90 (43 FR 1224).

The agency agrees that there were some contradictory statements in the previous tentative final rule regarding final formulation testing. The agency clarifies in this amended tentative final monograph that all final formulations are required to meet the specifications in the monograph. The agency has provided a test for effectiveness of OTC first aid antiseptics in § 333.70 of the tentative final monograph (as described in comment 56) to be followed by manufacturers for testing the final formulations of OTC first aid antiseptic drug products. The data are not required to be submitted to FDA by the manufacturer. The agency intends to use the testing procedures set forth in the final monograph for any necessary compliance testing of these products. Products that do not meet the specifications in § 333.70 when tested according to the testing procedures set forth in that section or otherwise approved through the petition process described in § 333.70(f) will be considered in violation of the final regulation.

58. Numerous comments addressed the agency's modifications in the Panel's proposed testing guidelines (43 FR 1239

to 1240), the agency's statements on final formulation testing (43 FR 1211, 1224, and 1240), and specific protocols for upgrading an antimicrobial ingredient from Category III to Category I (43 FR 1242 to 1246). Stating that the testing guidelines were unclear and pointing out inconsistencies between the guidelines and the agency's responses to comments at 43 FR 1211 and 1223 to 1227, a number of comments requested clarification or proposed modifications of a number of items in the guidelines.

Several comments requested specific information or submitted protocols for testing Category III ingredients. One comment requested that manufacturers be permitted to determine which protocol to follow to establish safety or effectiveness of an ingredient. A number of comments objected to the agency's consideration of the testing guidelines as final, and urged revisions in the guidelines for publication in the **Federal Register.**

The agency acknowledges that there were some inconsistencies in the testing guidelines for safety and effectiveness proposed in the previous tentative final rule. The agency does not consider the previous testing guidelines as final. The agency is proposing in this amended tentative final monograph a test for final formulations of first aid antiseptic drug products. (See comment 56 above.) Manufacturers may propose other appropriate testing procedures for inclusion in the monograph, and these will be evaluated by the agency upon request. Suggested safety and effectiveness testing procedures of Category III ingredients not in a final formulation are described in the previous tentative final monograph. (See 43 FR 1240.) Because the agency intends to use the testing procedures set forth in the final monograph (and proposed in § 333.70) for any necessary compliance testing of first aid antiseptic drug products covered by the monograph, manufacturers may also use these procedures to test a formulated product containing a Category III ingredient. The test results could be submitted to the agency as part of the information described in the previous tentative final monograph (43 FR 1240) to support the safety and effectiveness of these ingredients.

59. One comment argued that all requirements for preservative testing and data retention under proposed § 333.65 are outside the scope of the OTC drug review rulemaking procedure and should be deleted from the monograph. The comment pointed out that the agency stated in the tentative final monograph that the present framework of the OTC drug review does not permit a review of inactive ingredients, such as preservatives (43 FR 1218). The comment also stated that preservatives by definition are inactive ingredients (43 FR 1214) and as such are not covered by the monograph. Consequently, the comment concluded it is inconsistent with current policy to retain the requirements in § 333.65 of the monograph. The comment requested that all references to preservative testing be deleted from the monograph, especially because these requirements are already covered by the current good manufacturing practice regulations (21 CFR part 211).

Another comment stated that tests to determine the effectiveness of preservative concentration of antimicrobial ingredients are appropriate. However, this comment, as well as another comment, objected to the data retention requirement in proposed § 333.65(c), pointing out that such a requirement exceeds the agency's inspection authority under the act. The comment stated that "defining regulations for topical antimicrobial products cannot be used as a vehicle for expanding the scope of the statute."

Several comments objected to the definition of antimicrobial preservative under § 333.3(b) and requested that it be modified in the following areas: Limiting the preservative to the minimum effective concentration, the requirement for lack of contribution to the claimed drug effects of the product, and the reference to "inadvertently added microorganisms."

Several comments objected to the modifications of the testing procedures as detailed in § 333.65 (a) and (b) from those in the "U.S.P. Antimicrobial Preservative Effectiveness Test" (Ref. 1) and the "CTFA Preservative Test" (Ref. 2). Stating that various parts of these modifications were incongruous, unclear, and conflicting, the comments requested that the U.S.P. and CTFA tests be retained without modifications.

The agency agrees that preservatives are considered inactive ingredients and, upon further review, concludes that it is not necessary to include preservative testing in the tentative final monograph for antimicrobial drug products. However, preservative ingredients must meet the provisions of 21 CFR 330.1(e). The testing procedures detailed in the "U.S.P. Antimicrobial Preservative Effectiveness Test" (Refs. 1 and 3) and the "CTFA Preservative Test" (Ref. 2) are adequate. Therefore, previously proposed §§ 333.3(b) and 333.65 are not being included in this amended tentative final monograph. FDA encourages drug manufacturers to use the U.S.P. and CTFA tests to assure the adequacy of preservative systems in individual products. In view of this action, it is not necessary to respond to the other comments regarding preservative testing.

References

(1) "United States Pharmacopeia XIX," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 587, 1975.

(2) "Determination of Adequacy of Preservation of Cosmetic and Toiletry Formulations," CTFA Technical Guidelines, The Cosmetic, Toiletry and Fragrance Association, Inc., Washington, DC, 1983.

(3) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1478, 1989.

II. The Agency's Amended Tentative Final Monograph

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

The agency has carefully reviewed the claimed active ingredients submitted to this administrative record (Docket No. 75N–0183) including the advance notice of proposed rulemaking (39 FR 33103) and previous tentative final rule (47 FR 1210) for OTC topical antimicrobial drug products, the advance notice of proposed rulemaking for OTC topical alcohol drug products (47 FR 22324), and the advance notice of proposed rulemaking for OTC topical mercury-containing drug products (47 FR 436). Based upon the proposed definition of a first aid antiseptic discussed in comment 13, the agency has made a tentative classification for first aid antiseptic active ingredients.

In arriving at these classifications, the agency has considered all the available data and information, including an assessment of currently marketed ingredients that are labeled or suggested for use as first aid antiseptics. The concentrations described are based upon submitted data. In each case the ingredient has been extensively marketed and used clinically.

Many of the ingredients included in the tabulation below are in Category II and Category III because of a lack of data on use as a first aid antiseptic. However, all the ingredients have been included, as a convenience to the reader. The agency specifically invites comment and additional data on these ingredients.

The agency published an advance notice of proposed rulemaking for mercury-containing drug products on

January 5, 1982 (47 FR 436). That notice, based upon the recommendations of the Miscellaneous External Panel, proposed to classify OTC mercury-containing drug products for topical antimicrobial use as not generally recognized as safe and effective and as being misbranded. The agency received no comments. The Panel classified the mercurial ingredients, as a group, in Category II; some for lack of safety, some for lack of efficacy, and others due to a lack of both safety and efficacy. However, the Miscellaneous External Panel required bactericidal effect for Category I classification as a topical antimicrobial. Based on the proposed definition of "first aid antiseptic," the agency concludes that ingredients having bactericidal and/or bacteriostatic effects are suitable for inclusion in Category I. The agency's criteria are consistent with the Antimicrobial Panel's definition of an antimicrobial (43 FR 1246), i.e., "A compound or substance that kills microorganisms or prevents or inhibits their growth and reproduction * * *." and with section 201(o) of the act (21 U.S.C. 321(o)), which states: "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

Acceptable first aid antiseptic ingredients must be in appropriate product forms to maintain the necessary prolonged contact with the skin in order to sustain their bacteriostatic action. Adequate bacteriostatic action can be demonstrated through in vitro studies. However, data from in vivo studies, such as the ones described for these products in the previous tentative final monograph (43 FR 1210 at 1242), would also be required for these ingredients to be classified in Category I. In light of these changes, the agency has placed those mercurial ingredients with submitted data, which were formerly in Category II solely for efficacy reasons, into Category III and invites interested persons to comment. These mercurial ingredients include calomel, merbromin, phenylmercuric nitrate, and ortho-hydroxyphenylmercuric chloride (mercufenol chloride). "Mercufenol Chloride" is the established name for "ortho-hydroxyphenylmercuric chloride" as listed in the 1991 edition of the "USAN and the USP dictionary of drug names" (Ref. 1). Mercufenol chloride is also discussed in comment 52.

Reference

(1) "USAN and the USP dictionary of drug names," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 369, 992, s.v. "Mercufenol Chloride."

Poloxamer 188 was included in the previous tentative final monograph as a "skin wound cleanser" (43 FR 1246); but, because this antimicrobial rulemaking contains only ingredients with antimicrobial activity and because poloxamer 188 has no such activity, it is not included in the updated tentative final monograph. Poloxamer 188 may be used as an inactive ingredient or pharmaceutical aid in OTC antimicrobial drug products.

The following list is included as a summary of the categorization of first aid antiseptic active ingredients proposed by the agency.

SUMMARY OF ANTIMICROBIAL ACTIVE INGREDIENTS [1]

Category I
Ingredients generally recognized as safe and effective for OTC first aid use within the established concentration(s)
Single Ingredients
Alcohol 48 to 95 percent [2]
Benzalkonium chloride 0.1 to 0.13 percent
Benzethonium chloride 0.1 to 0.2 percent
Hexylresorcinol 0.1 percent
Hydrogen peroxide topical solution U.S.P. [4]
Iodine tincture U.S.P.
Iodine topical solution U.S.P.
Isopropyl alcohol 50 to 91.3 percent [2]
Methylbenzethonium chloride 0.13 to 0.5 percent
Phenol 0.5 to 1.5 percent
Combinations
Eucalyptol 0.091 percent, menthol 0.042 percent, methyl salicylate 0.055 percent, and thymol 0.063 percent in 26.9 percent alcohol [4]
Complexes
Camphorated metacresol (3 to 10.8 percent camphor and 1 to 3.6 percent metacresol) in a ratio of 3:1 [4]
Camphorated phenol (10.8 percent camphor and 4.7 percent phenol) in a light mineral oil, U.S.P. vehicle [4]
Povidone-iodine complex 5 to 10 percent
Category II
Ingredients not generally recognized as safe for OTC first aid use
Single Ingredients
Ammoniated mercury [3]
Cloflucarban
Fluorosalan
Mercuric chloride (Mercury chloride) [3]
Mercuric oxide, yellow [3]
Mercuric salicylate [3]
Mercuric sulfide, red [3]
Mercury [3]
Mercury oleate [3]
Mercury sulfide [3]
Nitromersol [3]
Para-chloromercuriphenol [3]
Thimerosal [3]
Tribromsalan
Vitromersol [3]
Zyloxin [3]
Combinations and/or Complexes
None
Category III
Ingredients for which the available data are insufficient to make a final determination for OTC first aid use [1]
Single Ingredients
Benzyl alcohol [2]
Calomel (mercurous chloride) [3]
Chlorobutanol [2]
Chloroxylenol
Merbromin [3]
Mercufenol chloride (ortho-hydroxyphenylmercuric chloride, ortho-chloromercuriphenol) [3]
Phenylmercuric nitrate [3]
Secondary amyltricresols [4]
Triclocarban
Triclosan
Combinations and/or Complexes
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate) [4]
Iodine complex (phosphate ester of alkylaryloxy polyoxyethylene glycol)
Mercufenol chloride and secondary amyltricresols [4]
Nonylphenoxypoly (ethyleneoxy) ethaniodine
Poloxamer-iodine complex
Triple dye
Undecoylium chloride iodine complex

[1] All ingredients (unless otherwise noted) in Antimicrobial I Drug Products Advance Notice of Proposed Rulemaking (39 FR 33103) and Tentative Final Monograph (47 FR 1210).

[2] Alcohol Drug Products, Advance Notice of Proposed Rulemaking (47 FR 22324).

[3] Mercury-Containing Drug Products, Advance Notice of Proposed Rulemaking (47 FR 436).

[4] Not previously reviewed, but categorized in the amended Tentative Final Monograph.

2. Testing of Category II and Category III Conditions

Recommended testing procedures for evaluating the effectiveness of the complete formulation of a first aid antiseptic drug product are included in proposed § 333.70. Suggested effectiveness testing procedures for active ingredients not in a final formulation and suggested safety testing are described in the previous tentative final monograph (see 43 FR 1210 at 1240 to 1242).

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any topical antiseptic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the

Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations and in the Agency's Previous Recommendations

FDA has considered the comments and other relevant information and is amending the previous tentative final monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. The agency is proposing to amend the regulations for topical antimicrobial drug products for OTC human use by adding Subpart A—First Aid Antiseptic Drug Products to 21 CFR part 333 and by amending § 369.20 (21 CFR 369.20). A summary of the changes made by the agency in this amended tentative final monograph follows.

The agency is proposing that skin wound cleansers and skin wound protectants that contain active antimicrobial ingredients be deleted as separate drug product categories and be included in a new category identified as "first aid antiseptics." (See comment 13.) Ingredients that were classified Category I as skin wound cleansers have been classified in Category I as first aid antiseptics. These are benzalkonium chloride, benzethonium chloride, methyl benzethonium chloride, and hexylresorcinol.

2. The agency is proposing that the drug product category "skin antiseptic" be deleted as a separate category and be included in the drug product category identified as "first aid antiseptics." (See comment 13.)

3. A new statement of identity is proposed for the product categories of skin wound protectants, skin wound cleansers, and skin antiseptics. Products previously in those categories are to be identified as "first aid antiseptics." (See comment 9.)

4. The agency is including the following indication for first aid antiseptics: "First aid to help" (select one of the following: "Prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select one of the following: "Infection," "bacterial contamination," or "skin infection") "in minor cuts, scrapes, and burns." (See comment 16.)

Because OTC first aid antiseptics are used for the first aid treatment of minor cuts, scrapes, and burns, as are OTC first aid antibiotics, the agency believes that the indications for these two categories of drugs should be similar. The labeling being proposed for first aid antiseptics in this tentative final monograph, where appropriate, is consistent with the labeling adopted in the final monograph for OTC first aid antibiotic drug products (52 FR 47312). (See 21 CFR 333.150(b).)

With the inclusion of alcohol drug products in this rulemaking, labeling recommended for those products has also been incorporated into the first aid antiseptic labeling proposed in new § 333.50. (See comments 27, 28, 32, and 33.)

5. The agency is proposing the following definition for first aid antiseptics consistent with the indication for that drug product category: "An antiseptic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns." (See comment 13.)

6. The agency is proposing that skin wound cleansers and skin wound protectants without active antimicrobial ingredients do not fall within the scope of the antimicrobial rulemaking. (See comment 14.) Poloxamer 188 was included in the previous tentative final monograph as a "skin wound cleanser," but is not included in the updated tentative final monograph. This antimicrobial rulemaking will only contain ingredients with antimicrobial activity; poloxamer 188 has no such activity. This will not preclude the use of poloxamer 188 as an inactive ingredient or pharmaceutical aid in OTC antimicrobial drug products.

7. Proposed in vitro testing procedures for testing final formulations for use as first aid antiseptics are included in proposed § 333.70. The results need not be submitted to the agency. However, the agency intends to use these testing procedures for any necessary compliance testing. (See comment 57.)

8. The agency proposes to reclassify several ingredients that were placed in Category III either as skin wound cleansers, skin wound protectants, or skin antiseptics to Category I as first aid antiseptics. These ingredients are iodine (tincture and solution) and phenol (0.5 to 1.5 percent). (See comment 37 on iodine.) Phenol is being reclassified into Category I as a first aid antiseptic because the agency has reevaluated effectiveness data available to the agency from the literature and submissions to the Panel (OTC Volumes 020041, 020042, and 020043) which show that phenol (0.5 percent to 1.5 percent without limitation to its vehicle) meets the proposed effectiveness criteria provided in the definition of a first aid antiseptic.

9. The agency proposes to reclassify povidone-iodine complex and camphorated phenol from Category III as skin antiseptics to Category I as first aid antiseptics. (See comments 38 and 39 on povidone-iodine complex and comment 50 on camphorated phenol.)

10. The agency has placed several ingredients that were not reviewed in the previous tentative final monograph into Category I as first aid antiseptics based on data contained in comments to the previous tentative final monograph and information from other sources. These ingredients are hydrogen peroxide, camphorated metacresol (3 to 10.8 percent camphor and 1 to 3.6 percent metacresol in a ratio of 3 to 1), and a combination product containing eucalyptol 0.091 percent, menthol 0.042 percent, methyl salicylate 0.055 percent, and thymol 0.063 percent in 26.9 percent alcohol. Because chlorhexidine gluconate has never been marketed for use as a first aid antiseptic, it is not being included in the first aid antiseptic rulemaking. (See comments 34 on chlorhexidine gluconate, 36 on hydrogen peroxide, 51 on camphorated metacresol, and 54 on the combination product.)

11. Soaps containing antimicrobial ingredients are considered cosmetics when deodorancy or other cosmetic claims are the only claims made for the product. Deodorant labeling claims for antimicrobial soaps are not included in the amended tentative final monograph. (See comment 10.) Antimicrobial soap as a separate drug product category for first aid use is not being included in the amended tentative final monograph. The use of soaps containing antimicrobial ingredients and labeled for other uses, e.g., health care personnel hand washes, will be discussed in the segment of this rulemaking dealing with uses other than first aid in a future issue of the **Federal Register**. (See comments 10 and 19.)

12. Based upon the proposed definition of a first aid antiseptic, the agency has revised the labeling to eliminate several indications that were Category I in the previous tentative final monograph. These include "prevents skin infection," "controls infection," "degerming," "kills germs," "bacteriostatic," "bactericidal," "reduces the risk of infection and cross-infection," and "microbiocidal." (See comment 16.)

13. The directions for use are being revised to delete the phrase "after gentle washing with soap and water" because

alkaline soap may be inappropriate for use on damaged tissue. (See comment 20.)

14. The warnings in § 333.92(c)(4) "do not bandage tightly" and in § 333.99(c), which stated "the warning 'Do not use solution with occlusive dressing' may be used instead of the warning 'do not bandage tightly,' " which were proposed for all skin wound cleansers, are not being required for all first aid antiseptic drug products. This includes products containing benzalkonium chloride, benzethonium chloride, and methylbenzethonium chloride. The need for such warnings will be separately evaluated for each ingredient based on the ingredient's sensitizing and irritation potential. (See comment 22.)

15. The warning "Do not bandage" is being required for camphorated metacresol, camphorated phenol, and phenol. (See comments 50 and 51.)

16. The agency proposes to revise the warning "This product is not for use on wild or domestic animal bites. If you have an animal bite, consult your physician immediately." Rather than having the separate warning for animal bites, the agency is proposing to add the term "animal bites" to the warning that lists other conditions that need medical attention. The revised warning is as follows: "In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor." (See comment 23.)

17. The agency proposes to revise and consolidate the warnings for skin wound cleansers, skin wound protectants, and skin antiseptics regarding the length of time these products can be used before consulting a physician. The previous tentative final monograph allowed 10 days of self-medication before consulting a physician. This amended tentative final monograph proposes 7 days for consistency with rulemakings for other topical products. The warning is also being revised so that it does not imply that these products are recommended to treat infection. The warning in § 333.93(c)(5) of the previous tentative final monograph that attempted to describe symptoms of infection to alert consumers when to consult a physician has been included in the new general warning in the amended tentative final monograph. The following warning replaces the separate warnings for the three drug products categories and is proposed for all first aid antiseptics, including alcohol: "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor." (See comment 24.)

18. The agency is eliminating several redundant or unnecessary warnings proposed in the previous tentative final monograph. The proposed warning in § 333.93(c)(7), "Do not use on chronic skin conditions such as leg ulcers, diaper rash, or hand eczema," has been deleted because the 1-week use limitation warning and the indication should be sufficient to inform the consumer that first aid antiseptics are not to be used on longstanding skin conditions. The proposed warning in § 333.93(c)(6), "Do not use in the eyes," has been expanded to include "or apply over large areas of the body," which is consistent with the first aid antibiotic tentative final monograph. (See comment 25.)

19. The agency proposes to revise the statement of identity for alcohol drug products proposed by the Miscellaneous External Panel in § 333.98(a) as "alcohol for topical antimicrobial use" to the same statement of identity as other first aid antiseptics, i.e., "first aid antiseptic." (See comment 27.)

20. The agency proposes to delete the warning proposed by the Miscellaneous External Panel in § 333.98(c)(2) for products containing isopropyl alcohol, "Use only in a well-ventilated area; fumes may be toxic." (See comment 32.)

21. The advance notice of proposed rulemaking for alcohol drug products for OTC topical antimicrobial use is being adopted by the agency with changes for clarity, and is being incorporated into this amended tentative final monograph. The lower limit of ethyl alcohol is being reduced to 48 percent because of evidence that 48 percent ethyl alcohol is effective as a first aid antiseptic. (See comment 33.) The indications for alcohol and isopropyl alcohol are being modified for consistency with the other Category I first aid antiseptic ingredients. (See comment 33.)

22. The agency is proposing to change the minimum concentration of povidone-iodine for effectiveness from 7.5 percent to 5 percent because of data from studies on a marketed product showing effectiveness at the lower concentrations. (See comment 39.)

23. The agency is eliminating the requirement that iodophors carry a 2-year expiration date. (See comment 40.)

24. The agency is reclassifying povidone-iodine for first aid antiseptic use to Category I. (See comments 41 and 42.)

25. The agency is proposing to change the upper limit of the concentration for methylbenzethonium chloride to 1:200 (0.5 percent). (See comment 45.) In addition, the agency is proposing to change the upper limit for benthezonium chloride to 1:500 (0.2 percent) based on the recommendation of the Miscellaneous External Panel in its report on OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis, published in the **Federal Register** of December 3, 1982 (47 FR 54646).

26. The agency is removing the proposed restriction that dosage forms of triclosan be formulated only in a bar soap. (See comment 48.)

27. The agency is proposing to allow the combination of a Category I antimicrobial ingredient with a Category I analgesic, anesthetic, or antipruritic ingredient or with a Category I skin protectant ingredient. Therefore, new § 333.20 is being proposed in this amended tentative final monograph to include these combinations. (See comment 49.)

28. The agency is not including previously proposed §§ 333.3(b) and 333.65 in the amended tentative final monograph. Nevertheless, the agency encourages manufacturers to continue to test preservatives according to USP and CTFA tests to assure the adequacy of preservative systems in individual products. (See comment 59.)

29. The term "scrapes" has been substituted for the term "abrasions" in the labeling of the amended tentative final monograph for first aid antiseptics, which is consistent with the first aid antibiotic monograph.

30. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This amended tentative final monograph proposes that option. (See § 330.50(e).)

31. Several mercury-containing OTC topical antimicrobials have been reclassified from Category II to Category III for effectiveness. Mercurial ingredients placed in Category II for safety are not being reclassified. The ingredients being reclassified are calomel, merbromin, mercufenol chloride, and phenylmercuric nitrate. (See Part II. A.1.—Summary of Ingredient Categories.) This change is being made in keeping with the revised effectiveness criteria for the drug product category "first aid antiseptic" (see comment 56), which were not available at the time the Miscellaneous External Panel evaluated the effectiveness of mercurial ingredients.

32. The agency is proposing to remove a portion of § 369.20 applicable to OTC first aid antiseptic drug products when the final monograph eventually becomes effective because this portion of the regulations will be superseded by the final monograph (part 333, subpart A; proposed in the Federal Register of July 9, 1982 (47 FR 29986)). The item proposed for removal is the entry for "ANTISEPTICS FOR EXTERNAL USE" in § 369.20.

The agency recognizes that there are other portions of §§ 369.20 and 369.21 applicable to OTC first aid antiseptic drug products that will also be removed eventually, but not necessarily at the time the first aid antiseptic final monograph becomes effective. These items include the entries for "CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE," "CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE," and "MERCURY PREPARATIONS FOR EXTERNAL USE" in § 369.20 and the entry for "ALCOHOL RUBBING COMPOUND" in § 369.21. These entries are also applicable to other OTC drug rulemakings and will not be removed until all the applicable rulemakings become final.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC first aid antiseptic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC first aid antiseptic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC first aid antiseptic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC first aid antiseptic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on first aid antiseptic drug products, a period of 180 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before January 21, 1992, submit to the Dockets Management Branch written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before January 21, 1992. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before July 22, 1992, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 22, 1992. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on September 22, 1992. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects

21 CFR Part 333

Labeling, Over-the-counter drugs, Topical antimicrobial drug products.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in parts 333 and 369 as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. New subpart A, consisting of §§ 333.1 through 333.70, is added to read as follows:

Subpart A—First Aid Antiseptic Drug Products

Sec.

Sec.

Subpart A—First Aid Antiseptic Drug Products

§ 333.1 Scope.

(a) An over-the-counter first aid antiseptic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.3 Definitions.

As used in this subpart:

(a) *Antiseptic drug.* In accordance with section 201(o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(o)), "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

(b) *First aid antiseptic.* An antiseptic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

§ 333.10 First aid antiseptic active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient, and the product is labeled according to §§ 333.50 or 333.60:

(a) Alcohol 48 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20.

(b) Alcohol 26.9 percent when combined in accordance with § 333.20(c).

(c) Benzalkonium chloride 0.1 to 0.13 percent.

(d) Benzethonium chloride 0.1 to 0.2 percent.

(e) Camphorated metacresol (camphor 3 to 10.8 percent and metacresol 1 to 3.6 percent in a ratio of 3 parts camphor to 1 part metacresol).

(f) Camphorated phenol (camphor 10.8 percent and phenol 4.7 percent) in a light mineral oil, U.S.P. vehicle.

(g) Eucalyptol 0.091 percent when combined in accordance with § 333.20(c).

(h) Hexylresorcinol 0.1 percent.

(i) Hydrogen peroxide topical solution U.S.P.

(j) Iodine tincture U.S.P.

(k) Iodine topical solution U.S.P.

(l) Isopropyl alcohol 50 to 91.3 percent by volume in an aqueous solution.

(m) Menthol 0.042 percent when combined in accordance with § 333.20(c).

(n) Methylbenzethonium chloride 0.13 to 0.5 percent.

(o) Methyl salicylate 0.055 percent when combined in accordance with § 333.20(c).

(p) Phenol 0.5 to 1.5 percent.

(q) Povidone-iodine 5 to 10 percent.

(r) Thymol 0.063 percent when combined in accordance with § 333.20(c).

§ 333.20 Permitted combinations of active ingredients.

(a) Any single first aid antiseptic active ingredient identified in § 333.10 may be combined with any single external analgesic active ingredient identified in § 348.10(a) of this chapter provided the product is labeled according to § 333.60.

(b) Any single first aid antiseptic active ingredient identified in § 333.10 may be combined with any single skin protectant active ingredient identified in § 347.10 of this chapter provided the product is labeled according to § 333.60.

(c) The ingredients identified in § 333.10 (b), (g), (m), (o), and (r) may be combined provided the product is labeled according to § 333.60.

§ 333.50 Labeling of first aid antiseptic drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "first aid antiseptic."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "First aid to help" (select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select one of the following: "infection," "bacterial contamination," or "skin infection") "in minor cuts, scrapes, and burns." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 333.10.* (i) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor."

(ii) "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor."

(2) *For products containing any ingredient identified in § 333.10 (a) and (l).* "Flammable, keep away from fire or flame."

(3) *For products containing any ingredient identified in § 333.10 (e), (f), and (p).* "Do not bandage."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions":

(1) "Clean the affected area."

(2) *For products that are ointments, creams, and liquids.* "Apply a small amount of this product on the area 1 to 3 times daily."

(3) *For products labeled for use as a wet compress.* "Bandage lightly. Keep bandage wet with solution."

(4) *For products packaged as sprays.* "Spray a small amount of this product on the area 1 to 3 times daily."

(5) *For products containing any ingredient identified in § 330.10 (a), (b), (c), (d), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), and (r) of this chapter.* "May be covered with a sterile bandage."

(6) *For products packaged as liquids or sprays.* "If bandaged, let dry first."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

§ 333.60 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the

product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable over-the-counter (OTC) drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations identified in § 333.20(a).* In addition to the required indication identified in § 333.50, the labeling of the product may state, under the heading "Indications," the following additional indication: "First aid for the temporary relief of" (select one of the following: "pain," "discomfort," "pain or discomfort," or "pain and itching") "in minor cuts, scrapes, and burns."

(2) *For permitted combinations identified in § 333.20(b).* In addition to the required indication identified in § 333.50, the labeling of the product may state, under the heading "Indications," the following additional indication: "First aid for the temporary protection of minor cuts, scrapes, and burns."

(3) *For permitted combinations identified in § 333.20(c).* The indications in § 333.50 should be used.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated below. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

§ 333.70 Testing of first aid antiseptic drug products.

A first aid antiseptic drug product in a form suitable for topical application will be recognized as effective if it contains an active ingredient included in § 333.10 and if at its lowest recommended use concentration it decreases the number of bacteria per milliliter in *Staphylococcus aureus* (ATCC No. 6538), *Escherichia coli* (ATCC No. 8739), and *Pseudomonas aeruginosa* (ATCC No. 9027) cultures (available from American Type Culture Collection (ATCC), 12301 Parklawn Dr., Rockville, MD 20852) by 3 $\log_{10}$ within 10 minutes at 32 °C in the presence of 10 percent serum in vitro. Drugs identified in § 333.10 (j), (k), and (l) are exempt from this testing procedure. Furthermore, an antiseptic drug product for inhibitory use as a wet dressing, ointment, dusting powder, or such other use involving prolonged contact with the body, will be recognized as effective if its active ingredient is included in § 333.10 and if a 1:120 dilution of the formulated drug product in growth medium without neutralizers prevents an increase in the number of organisms from an inoculum of 10^8 organisms of the above cultures when incubated at 32 °C for 48 hours. First aid antiseptic drug products that are not exempt from this provision must meet the specified requirements when tested in accordance with the following procedures unless a modification is approved as specified in paragraph (e) of this section.

(a) *Laboratory facilities, equipment, and reagents*—(1) *laboratory facilities.* To prevent the contamination of test microorganism cultures with extraneous microorganisms, perform the test using aseptic techniques in an area as free from contamination as possible. Because test cultures of microorganisms may be adversely affected by exposure to ultraviolet light or chemicals in aerosols, do not test under direct exposure to ultraviolet light or in areas under aerosol treatment. Do environmental tests to assess the suitability of the testing environment frequently enough to assure the validity of test results.

(2) *Equipment.* Use laboratory equipment that is adequate for its intended use. Thoroughly cleanse the equipment after each use to remove any antiseptic residues. Keep the equipment covered when not in use. Sterilize clean glassware intended for holding and transferring the test organisms in a hot air oven at 200 to 220 °C for 2 hours. Use volumetric flasks, pipets, or accurately calibrated diluting devices when diluting standard and sample solutions. Use plastic or glass Petri dishes having dimensions of 20×100 millimeters. Use covers of suitable material.

(3) *Reagents*—(i) *Phenol stock solution.* Prepare a 5-percent weight to volume solution of phenol by the method described in the "Official Methods of Analysis of the Association of Official Analytical Chemists," Kenneth Helrich (ed.), 15th Ed., 1990, pp. 133–134, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201–3301, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(ii) *Serum.* Use inactivated fetal bovine serum without added preservatives and/or anti-infective products.

(b) *Culture media and diluting fluids*—(1) *Ingredients.* Use Soybean-Casein Digest Medium for culture media and diluting fluids that conform to the standards prescribed by "The United States Pharmacopeia XXII/The National Formulary XVII." In lieu of preparing the media from the individual ingredients, the media may be made from dehydrated mixtures which, when reconstituted with distilled water, have the same or equivalent composition as media prepared from individual ingredients. Media prepared from dehydrated mixtures is to have growth-promoting, buffering, and oxygen tension-controlling properties equal to or better than media prepared from individual ingredients. Adjust the pH of each medium with 1 Normal hydrochloric acid or sodium hydroxide before sterilization, if necessary, so that after sterilization the pH will fall within the specified range prescribed by "The United States Pharmacopeia XXII/The National Formulary XVII." Steam sterilize the media in an autoclave at 121 °C for 20 minutes.

(2) *Neutralizers.* When neutralizers are added to culture media and diluting fluid, perform the following tests.

(i) *Neutralizer inactivation of antiseptic test.* Assay the neutralizer

efficacy for the test antiseptic as follows: Prewarm the test antiseptic, culture medium, test culture, and serum to 32 °C by incubating appropriate volumes of all solutions in a water bath at 32 °C for 5 minutes. Mix 0.8 milliliter of antiseptic (for controls use 0.8 milliliter of sterile water) with 9.0 milliliters of culture medium containing an appropriate antiseptic neutralizer followed by the addition of 0.2 milliliter of the test culture in 50 percent serum. Incubate the mixture of cells, serum, antiseptic, and neutralizer at 32 °C for 10 minutes. Remove aliquots, dilute, and assay for surviving bacteria by the plate-count assay method using diluting and plating media containing appropriate neutralizers, if required. Results obtained showing differences greater than 20 percent between test and control cultures indicate that the neutralizer used to inactivate the test antiseptic is ineffective. Reject results obtained from tests employing ineffective neutralization procedures.

(ii) *Neutralizer effect on bacteria viability test.* Test the effect of neutralizers used to inactivate antiseptic active ingredients on cell viability by diluting aliquots of each test organism culture in Medium A (without neutralizer), specified in paragraph (b)(3)(i) of this section, and in the appropriate diluting fluid (neutralizing medium), specified in paragraph (b)(4) of this section. Determine the number of bacteria in aliquots of appropriate dilutions by the plate-count assay method utilizing growth agar medium containing the same neutralizer concentration as the diluting medium. Determine neutralizer effects on cell viability by comparing the relative number of microorganisms growing on Medium B, specified in paragraph (b)(3)(ii) of this section, with and without added neutralizers. Results obtained showing differences greater than 20 percent between cultures diluted in medium with and without neutralizers indicate that, at the concentration utilized, the antiseptic neutralizer alters the determination of viable cells in the test cultures. Reject results obtained from tests in which the neutralizer employed alters the determination of viable cell numbers.

(3) *Culture media*—(i) *Medium A (without neutralizers).* Use soybean-casein digest fluid medium corresponding to that described in paragraph (b) of this section.

(ii) *Medium B.* Soybean-casein digest agar medium. Same as Medium A, except for the addition of 15 grams of agar per liter.

(iii) *Medium C.* Same as diluting fluid 1, except for the addition of 15 grams of agar per liter.

(iv) *Medium D.* Same as diluting fluid 2, except for the addition of 15 grams of agar per liter.

(v) *Medium E.* Same as diluting fluid 3, except for the addition of 15 grams of agar per liter.

(4) *Diluting fluids*—(i) *Diluting fluid 1.* Diluting medium for neutralizing quaternary ammonium and phenolic antiseptic ingredients. Same as Medium A, except for the addition of 5 grams of lecithin and 40 milliliters of polysorbate 20 per liter.

(ii) *Diluting fluid 2.* Diluting medium for neutralizing iodophor antiseptic ingredients. Same as Medium A, except for the addition of 5 grams of sodium thiosulfate per liter.

(iii) *Diluting fluid 3.* Diluting medium for neutralizing mercurial antiseptic ingredients. Same as Medium A, except for the addition of 1 gram of sodium thioglycollate and 2.5 grams of sodium bisulfite per liter.

(c) *Test organisms.* (1) Use cultures of the following microorganisms:

(i) *Staphylococcus aureus* (ATCC No. 6538).

(ii) *Pseudomonas aeruginosa* (ATCC No. 9027).

(iii) *Escherichia coli* (ATCC No. 8739).

(2) *Preparation of suspension.* Maintain stock cultures on Medium B agar slants by monthly transfers. Alternatively, cultures may be lyophylized and stored at −70 °C. Incubate new stock transfers 2 days at 32 °C; then store at 2 to 5 °C. From stock culture, inoculate tubes of Medium A and make at least 4 but less than 30 consecutive daily transfers in Medium A, incubating at 32 °C, before using the culture for testing. Use a 22- to 26-hour culture of organisms grown in Medium A at 32 °C for the test.

(3) *Determination of cell number in broth cultures.* Prepare serial 1:10 dilutions of each culture in Medium A and determine the number of cells per milliliter of culture by the plate-count assay method. Do not use cultures stored at 4 °C for more than 48 hours for assay. Do not use cultures containing less than 10^9 cells per milliliter.

(4) *Plate-count assay.* For each culture to be assayed, pipet 1 milliliter of each prepared dilution into each of two sterile Petri plates. To each plate, add 20 milliliters of sterile Medium B that has been melted and cooled to 45 °C (if neutralizers are required, use the corresponding agar growth medium with the appropriate neutralizer). Mix the sample with the agar by tilting and rotating the plate and allow the contents to solidify at room temperature. Invert the Petri plates and incubate at 32 °C for 48 hours. Following incubation, count the number of developing colonies. Use Petri plates containing between 30 and 300 colonies in calculating the number of bacteria per milliliter of original culture.

(5) *Test organism antiseptic resistance test.* To insure that antiseptic resistance properties of each organism have not altered substantially, determine the resistance to phenol at 20 °C for each organism as described in "Phenol Coefficient Methods" referenced in paragraph (a)(3) of this section.

(i) *Escherichia coli.* A culture of *Escherichia coli* (ATCC No. 8739) is satisfactory for test purposes if it has resistance to phenol at 20 °C at least as follows:

Phenol	5 min	10 min	5 min
1:90 dilution...	+ or 0	+ or 0	0
1:100 dilution.	+	+	+ or 0

(ii) *Pseudomonas aeruginosa.* A culture of *Pseudomonas aeruginosa* (ATCC No. 9027) is satisfactory for test purposes if it has resistance to phenol at 20 °C at least as follows:

Phenol	5 min	10 min	15 min
1:80 dilution...	+ or 0	+ or 0	0
1:90 dilution...	+	+	+

(iii) *Staphylococcus aureus.* A culture of *Staphylococcus aureus* (ATCC No. 6538) is satisfactory for test purposes if it has resistance to phenol at 20 °C at least as follows:

Phenol	5 min	10 min	15 min
1:60 dilution...	+ or 0	+ or 0	0
1:70 dilution...	+ or 0	+	+

(d) *Test procedures*—(1) *Method 1*—(i) *Method validation.* This test is valid only for those antiseptics that are water soluble and/or miscible and that can be neutralized by one of the subculture media specified in paragraphs (b)(3) and (b)(4) of this section or that can be overcome by dilution.

(ii) *Bactericidal assay procedure.* Prewarm all test solutions by incubating appropriate volumes at 32 °C in a water bath for 5 minutes. Pipet 1.0 milliliter of serum, 1.0 milliliter of appropriate bacterial test culture, and 8.0 milliliters of test antiseptic at its recommended use concentration into a medication tube and mix well. Incubate at 32 °C for 10

minutes. Remove triplicate 1-milliliter sample aliquots and dilute in Medium A containing appropriate neutralizers. Determine the number of surviving organisms per milliliter of test culture by the plate-count method using plating media containing appropriate neutralizers, if required.

(iii) *Bacteriostatic assay procedure.* Prewarm all test solutions by incubating appropriate volumes at 32 °C in a water bath for 5 minutes. Pipet 1.0 milliliter of serum, 1.0 milliliter of appropriate bacterial test culture and 8.0 milliliters of test antiseptic at its recommended use concentration into a medication tube and mix well. Pipet 1.0 milliliter aliquots of this test mixture into triplicate medication tubes containing 100 milliliters of Medium A without neutralizers and mix well. Incubate at 32 °C for 48 hours and determine the number of organisms per milliliter of culture by the plate-count method.

(2) [Reserved]

(e) *Test modifications.* The formulation or mode of administration of certain products may require modification of the testing procedures in this section. In addition, alternative assay methods (including automated procedures) employing the same basic chemistry or microbiology as the methods described in this section may be used. Any proposed modification or alternative assay method shall be submitted as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative assay method provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in part 20 of this chapter.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

3. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.20 [Amended]

4. Section 369.20 *Drugs; recommended warning and caution statements* is amended in subpart B by removing the entry for "ANTISEPTICS FOR EXTERNAL USE."

Dated: May 20, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-17107 Filed 7-19-91; 8:45 am]

BILLING CODE 4160-01-M

federal register

Monday
July 22, 1991

Part V

Department of Education

Office of Special Education Programs; Final Priority for Training Personnel for the Education of Individuals With Disabilities Program; Notice

DEPARTMENT OF EDUCATION

[CFDA No.: 84.029]

Office of Special Education Programs; Final Priority for Training Personnel for the Education of Individuals With Disabilities Program

AGENCY: Department of Education.

ACTION: Notice of final priority for Training Personnel for the Education of Individuals with Disabilities Program (FY 1991).

SUMMARY: The Secretary announces an additional priority for fiscal year (FY) 1991 under the Training Personnel for the Education of Individuals with Disabilities Program (84.029). This priority is in addition to those previously published on July 13, 1990 (55 FR 28874–5), and on February 6, 1991 (56 FR 4906–11). Under this priority the Secretary will support projects for the training of educational interpreters for students with hearing impairments including deafness.

EFFECTIVE DATE: This priority takes effect either 45 days after publication in the **Federal Register** or later if Congress takes certain adjournments. If you want to know the effective date of this priority call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Max Mueller, Division of Personnel Preparation, Office of Special Education Programs, Department of Education, 400 Maryland Avenue, SW., (Switzer Building, Room 3512–MS 2651) Washington, DC 20202. Telephone (202) 732–1554; (TDD (202) 732–1100).

SUPPLEMENTARY INFORMATION: On April 30, 1991, at 56 FR 19896, the Secretary published in the **Federal Register** a Notice of Proposed Funding Priority for fiscal year 1991, for the Training of Personnel for the Education of Individuals with Disabilities (IDEA). Based on that notice, the Secretary establishes a FY 1991 priority for the personnel preparation discretionary grant program to implement language in the Senate appropriations committee report for 1991 concerning additional projects for training interpreters under section 631(a) of Part D of the Individuals With Disabilities Education Act (Grants for Personnel Training).

The publication of this priority does not preclude the Secretary from publishing additional priorities, nor does it limit the Secretary to funding only this priority, subject to meeting applicable rulemaking requirements.

Public Comment

In the April 30, 1991 issue of the **Federal Register**, the Secretary invited comments on the proposed priority.

Analysis of Comments and Changes

A total of eight respondents commented on the proposed priority. No changes were made as a result of those comments.

General Comments

All commenters were strongly supportive of this priority.

Comment: One commenter suggested that the priority support establishment of one- and two-year interpreter training programs at the community college level.

Discussion: Community colleges are eligible applicants under this program, and there is no restriction on duration of programs. Therefore no changes are necessary.

Changes: None.

Comment: One commenter suggested that grants include the charge to develop and share materials among training programs.

Discussion: The Secretary encourages this activity, but has determined that it would not be appropriate to require it for all grants under this program. Adding responsibility for development and dissemination activities would substantially increase the cost of individual projects and consequently reduce the number of projects and the number of personnel being trained. In addition, many potential applicants who are quite capable of delivering quality training programs may not have the qualifications to take on development efforts. Therefore, it is not appropriate to require this of grantees for this competition. Several other grant programs managed by the Department are available to address the issue of development more directly.

Changes: None.

Comment: One commenter suggested that grants be for a minimum of $100,000.

Discussion: This figure falls within the range of grants typically awarded under the personnel preparation program, but not as a minimum. The Secretary has no data to suggest that training of interpreters is significantly more expensive than training other related services personnel. The issue of funding level is not a topic of the priority, but the program announcement indicates a range of funding of approximately $60,000 to $100,000.

Changes: None.

Comment: Two commenters suggested that priority be given to programs that will lead to certificates or degrees.

Discussion: This is a general requirement of the personnel preparation program. It is not necessary to specify further in the priority.

Changes: None.

Comment: One commenter suggested that the program focus on programs at the community college level.

Discussion: Community colleges are eligible applicants under the program. However, the Secretary does not feel that it is necessary or appropriate to restrict the competition.

Changes: None.

Comment: One commenter believed that the proposed priority was limited to training interpreters for services at the elementary and secondary school level, and urged that it should include attention to the need for interpreters at the post-secondary level.

Discussion: The priority addresses the need for interpreters for children with hearing impairments, including deafness, but is not limited to the elementary and secondary school level.

Changes: None.

Comment: One commenter suggested that the priority be implemented through a mentor program.

Discussion: A program built on a mentor model would be appropriate for consideration under this priority. However, the Secretary sees no reason to limit the competition to any particular training model.

Changes: None.

Comment: Two commenters suggested reserving two of the anticipated grants for training of cued speech interpreters, or that each grant be required to provide training in all primary modes of communication, or both.

Discussion: Training of interpreters under this priority is not limited to any particular mode of interpreting. The needs in various areas are not necessarily the same, nor are the capabilities of all eligible training programs. The Secretary does not feel that it would be fair to potential applicants or the ultimate beneficiaries of the program to insist that programs cover all types of interpreting or to reserve funds for specific numbers of projects of various types.

Changes: None.

Comment: One commenter suggested funding a cued speech consulting unit to assist supported projects.

Discussion: The authority under IDEA Section 631(a) does not extend to support of technical assistance activities such as consulting units.

Changes: None.

Priority

Under 34 CFR 75.105(c)(3) the Secretary will give an absolute preference to applications that meet the following priority. The Secretary will fund under this competition only applications that meet this absolute priority.

Background

The Secretary will award 12 to 15 grants to support the preservice training of educational interpreters for children with hearing impairments, including deafness. The Department and the Congress have recognized that one of the most severe problems faced by schools in providing services for these children is obtaining qualified personnel to interpret. The problem is at least two-fold: (1) The availability of interpreters in general is quite limited in relation to the needs of children with hearing impairments; and (2) even those interpreters who are available are often untrained or inadequately trained to meet the specific demands of interpreting and working in an instructional setting. The problem is exacerbated by the increasing integration of children with hearing impairments into regular education settings. Integration requires more interpreters than the previous practice of placing children with hearing impairments into segregated classes or schools because of the increased interpreter to student ratio required.

Training Interpreters

In response to this need, the Training Personnel for the Education of Individuals with Disabilities Program will give an absolute priority for support of projects to increase the supply of educational interpreters. Support will be limited to projects that demonstrate recruitment strategies, specifically adapted curricula, and incentives designed to increase the probability of program graduates' functioning productively as interpreters in instructional settings. These projects must be concentrated on student support, rather than on basic institutional support.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for these programs.

(Catalog of Federal Domestic Assistance Number 84.029: Training Personnel for the Education of Individuals with Disabilities)

Program Authority: 20 U.S.C. 1431.

Dated: June 17, 1991.

Lamar Alexander,

Secretary of Education.

[FR Doc. 91-17308 Filed 7-19-91; 8:45 am]

BILLING CODE 4000-01-M

Federal Register

Monday
July 22, 1991

Part VI

Department of the Interior

Bureau of Indian Affairs

Receipt of Petition for Federal Acknowledgment of Existence as an Indian Tribe; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Receipt of Petition for Federal Acknowledgment of Existence as an Indian Tribe

July 3, 1991.

This is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Pursuant to 25 CFR 83.8(a) (formerly 25 CFR 54.8(a)) notice is hereby given that the Little River Band of Ottawa Indians, c/o Bonnie L. Kenny, 238 Parkdale Avenue, Manistee, MI 49660 has filed a petition for acknowledgment by the Secretary of the Interior that the group exists as an Indian tribe. The petition was received by the Bureau of Indian Affairs (BIA) on June 4, 1991, and was signed by members of the group's governing body.

This is a notice of receipt and does not constitute notice that the petition is under active consideration. Notice of active consideration will be sent by mail to the petitioner and other interested parties at the appropriate time.

Under § 83.8(d) (formerly § 54.8(d)) of the Federal regulations, interested parties may submit factual and/or legal arguments in support of or in opposition to the group's petition. Any information submitted will be made available on the same basis as other information in the BIA's files. Such submissions will be provided to the petitioner upon receipt by the BIA. The petitioner will be provided an opportunity to respond to such submissions prior to a final determination regarding the petitioner's status.

The petition may be examined by appointment in the Department of the Interior, Bureau of Indian Affairs, Branch of Acknowledgment and Research, room 1362–MIB, 1849 C Street, NW., Washington, DC 20240, Phone: (202) 208–3592.

William D. Bettenberg,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 91–17285 Filed 7–19–91; 8:45 am]

BILLING CODE 4310–02–M

federal register

Monday
July 22, 1991

Part VII

Department of Transportation

Federal Aviation Administration

14 CFR Part 23

Small Airplane Airworthiness Review Program Notice No. 3; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. 26344; Notice No. 90-23B]

Small Airplane Airworthiness Review Program Notice No. 3

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Reopening of comment period.

SUMMARY: This notice announces the reopening of the comment period for the Notice of Proposed Rulemaking (NPRM) for powerplant and equipment airworthiness standards for normal, utility, acrobatic and commuter category airplanes. The reopening responds to a request from the General Aviation Manufacturers Association (GAMA). The reopening is needed to permit GAMA additional time to comment upon the NPRM.

DATES: Comments must be received on or before August 21, 1991.

ADDRESSES: Comments on this notice may be mailed in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-10), Docket No. 26344, 800 Independence Avenue SW., Washington, DC 20591, or delivered in triplicate to room 915G, 800 Independence Avenue SW., Washington, DC 20591. Comments delivered must be marked Docket No. 26269. Comments may be inspected in room 915G between 8:30 a.m. and 5 p.m. on weekdays, except on Federal holidays.

In addition, the FAA is maintaining an information docket of comments in the Office of the Assistant Chief Counsel, ACE-7, Federal Aviation Administration; Central Region, 601 East 12th Street, Kansas City, Missouri 64106. Comments in the information docket may be inspected in the Office of the Assistant Chief Counsel weekdays, except Federal holidays, between the hours of 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph H. Snitkoff, Acting Manager, Standards Office (ACE-110), Aircraft Certification Service, Central Region, Federal Aviation Administration, room 1544, 601 East 12th Street, Federal Office Building, Kansas City, Missouri 64106; telephone (816) 426-5688.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to submit such written data, views, or arguments as they may desire concerning NPRM 90-23. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this notice are also invited. Substantive comments should be accompanied by cost estimates. Comments should identify the regulatory docket or notice number and should be submitted in triplicate to the Rules Docket address specified above. All comments received on or before the closing date for comments specified will be considered by the Administrator before taking action on this proposed rulemaking. The proposals contained in this notice may be changed in light of comments received. All comments received will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each substantive public contact with Federal Aviation Administration (FAA) personnel concerned with this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments in response to this notice must include a preaddressed, stamped postcard on which the following statement is made: "Comments to Docket No. 26344." The postcard will be date stamped and mailed to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM 90-23 by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-230, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify NPRM 90-23.

Background

On September 17, 1990, the FAA issued NPRM 90-23 (55 FR 40598, October 3, 1990). The NPRM proposed changes in the powerplant and equipment airworthiness standards for normal, utility, acrobatic and commuter category airplanes. These proposals resulted from the Small Airplane Airworthiness Review Conference held on October 22-26, 1984, in St. Louis, Missouri.

By letter dated March 22, 1991, the Joint Aviation Authority (JAA) requested that the comment period be extended in order to enable the JAA-23 Study Group time to coordinate a European position. Since the JAA request was received after the comment period closed, the comment period for this notice was reopened to July 2, 1991, to accommodate the JAA request.

On July 1, 1991, GAMA requested that the comment period be extended in order to accommodate comments forwarded to GAMA from its members. The request was received too late to extend the comment period; therefore, the comment period needs to be reopened to accommodate their request.

Conclusion

In view of the possibility of obtaining additional technical information and to provide for a more consistent set of airworthiness standards, the FAA agrees that it would be in the public interest to grant GAMA's request to reopen the comment period. Accordingly, the comment period for NPRM 90-23 is reopened until August 21, 1991.

List of Subjects in 14 CFR Part 23

Aircraft, Air transportation, Aviation safety, Safety.

Issued in Washington, DC, on July 16, 1991.

David W. Ostrowski,

Acting Director, Aircraft Certification Service.

[FR Doc. 91-17327 Filed 7-19-91; 8:45 am]

BILLING CODE 4910-13-M

federal register

Monday
July 22, 1991

Part VIII

Department of Health and Human Services

Agency for Toxic Substances and Disease Registry

Identification of Priority Need for Phenol, Chloroethane, Carbon Tetrachloride and Isophorone; Response to Public Comments; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency For Toxic Substances and Disease Registry

[ATSDR-38]

Response to Public Comments for Identification of Priority Data Needs for Phenol, Chloroethane, Carbon Tetrachloride and Isophorone

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Public Health Service (PHS), Department of Health and Human Services (DHHS).

ACTION: Notice.

SUMMARY: This notice contains ATSDR's response to the comments received on the "Identification of Priority Data Needs for Phenol, Chloroethane, Carbon Tetrachloride and Isophorone," which was published in the **Federal Register** on March 28, 1990 (55 FR 11566). This notice also includes a revised draft copy of the Priority Data Needs Document for Carbon Tetrachloride to illustrate the changes and improvements in these documents.

ATSDR received comments from industry, academic institutions, private chemical associations and other government agencies concerning both programmatic and substance-specific issues pertaining to the implementation of the research program. In response to the comments from the public, STSDR has prepared a document that identifies submitters of public comments and provides the Agency's response to comments regarding implementation of the research program and substance-specific issues for each of the pilot substances.

ATSDR has identified four major issues as a result of comments received from the public relating to implementation of the research program. These four issues are presented below along with the Agency's responses. Based on these concerns, and others expressed internally, and by the Environmental Protection Agency (EPA) and the National Toxicology Program (NTP), ATSDR has revised the format of its Priority Data Needs Documents, which provide the background support for the Agency's determinations of priority data needs. ATSDR formerly referred to these documents as Decision Logic Documents.

ADDRESSES: Requests for the document Response to Public Comments for Identification of Priority Data Needs for Phenol, Chloroethane, Carbon Tetrachloride and Isophorone should bear the docket control number ATSDR-18, and should be submitted to the Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road NE., Atlanta, Georgia 30333.

This document will be available for public inspection at the Agency for Toxic Substances and Disease Registry, Building 33, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. until 4:30 p.m. Monday through Friday, except for legal holidays.

FOR FURTHER INFORMATION CONTACT: The Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road NE., Atlanta, Georgia 30333. Telephone: 404-639-6000.

SUPPLEMENTARY INFORMATION: The Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9604(i), as amended by the Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99-499)), requires that ATSDR (1) with EPA develop a list of hazardous substances found at National Priorities List (NPL) sites (in order of priority), (2) prepare toxicological profiles of these substances, and (3) assure the initiation of a research program to fill identified priority data needs associated with the substances.

ATSDR, in cooperation with EPA, has identified 250 hazardous substances that have been determined to pose the most significant potential threat to human health. Toxicological profiles have been developed for 130 of these substances. Each toxicological profile includes an examination, summary, and interpretation of available toxicological information on the substance and associated health effects. The profiles also include a determination of whether adequate information on the health effects of each substance is now available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a program of research designed to determine these health effects.

As the first step in developing and implementing a research program, ATSDR published a "Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles" (54 FR 37618). ATSDR then selected four pilot substances—phenol, chloroethane, carbon tetrachloride and isophorone for application of its Decision Guide. The selection of these four substances for this pilot exercise did not imply anything about their overall priority of concern with respect to health effects. The intent of the pilot exercise was to determine the adequacy of the Agency's procedures for identifying specific data needs for individual substances. The identified priority data needs for each of the pilot substances were reviewed by an interagency panel representing ATSDR, EPA, and NTP, and published in the **Federal Register** (55 FR 11566) with a ninety-day public comment notice (originally 45 days).

Four Major Issues Identified as a Result of Comments Received From the Public and ATSDR's Response

1. A record to support prioritization of data needs should be developed to document the application of the decision guide and conveyance of scientific rationale in the support documents.

Response

ATSDR will provide more information in the support documents that attend ATSDR's application of the Decision Guide (54 FR 37618) for individual hazardous substances. The support document will (a) provide a discussion on Procedures for identifying data needs, including a brief summary of the underlying logic for the collection of the data for various endpoints from the ATSDR Decision Guide, (b) describe the Purpose of the data and the Finding from the profile including key references, and (c) provide information on the Impact on Public Health of the individual hazardous substances. This section will also provide the scientific rationale for collecting the data to assist in performing health assessments. The support document will be separate from the toxicological profiles; the profile will still be required for more in-depth evaluation.

2. ATSDR should give a more thorough description of the exposure and toxicity data collection.

Response

Exposure: ATSDR will provide more detail on methods and scope of specific priority data needs where appropriate. Because of the breadth of the substance-specific research program, some exposure data needs would not be filled by classical toxicity testing and thus do not have "established guidelines" (e.g., analytical methods). For such priority data needs, ATSDR will not indicate specific methods for obtaining the data. When Level III research is needed for exposure or toxicity, ATSDR will not develop detailed methodologies. Rather, ATSDR will review protocols that address these data needs submitted by the sponsor or researcher. ATSDR will

coordinate the reviews with EPA and the NTP.

Toxicity: ATSDR will work with EPA and NTP to more fully define those testing needs in the support documents that have established guidelines, e.g., testing covered by the Toxic Substances Control Act (TSCA) guidelines or by NTP's immunotoxicity battery and chronic toxicity testing.

3. Human exposure information should be collected by ATSDR prior to health effect studies.

Response

ATSDR has concluded that it is generally best to address in parallel both priority exposure assessment and toxicity data needs. Requiring confirmation of exposure prior to the collection of health effects data would not be responsive to public health concerns at hand.

Any substance on ATSDR's list of hazardous substances must have been identified at NPL sites and possess potential for human exposure. Experience has shown ATSDR that consequential exposures to hazardous substances have occurred in the past, but have been interdicted; whereas, other exposures are currently on-going. Health outcomes as a result of past exposure may cause health effects, but the responsible substances are often no longer measurable. As for current exposures, appropriate method development and confirmation may take considerable time, or may not be feasible where such methods are lacking.

In addition, available environmental and human exposure information from NPL site files, ATSDR health assessments, and Agency exposure and health studies is being extracted into a database. This database will provide additional information on potential for human exposure to each hazardous substance.

4. Extrapolation methodology should be used for filling toxicity data needs across exposure routes or exposure durations.

Response

ATSDR has concluded that levels of significant human exposure are to be determined for each substance and the associated acute, subacute, and chronic health effects. In addition, the most relevant route of exposure at hazardous waste sites will be identified for the data need.

As a general practice, ATSDR does not currently extrapolate toxicity data across exposure routes or exposure durations. However, ATSDR acknowledges that such extrapolations may be done on a substance-by-substance basis after appropriate toxicokinetic information has been collected and evaluated. This will be discussed in each support document.

ATSDR Substance-Specific Applied Research Program

Priority Data Needs for:

CARBON TETRACHLORIDE

Prepared by: Agency for Toxic Substances and Disease Registry/ Division of Toxicology (ATSDR/DT)

I. Executive Summary

Carbon tetrachloride (CCl_4) appeared on the first priority list of hazardous substances identified by ATSDR and the Environmental Protection Agency (EPA) on April 17, 1987 (52 FR 12866). This list contains substances that have been identified at National Priorities List (NPL) sites and determined to pose a potential health risk based on (1) known or suspected human toxicity, (2) frequency of occurrence at NPL sites or other facilities, and (3) potential for human exposure to the substance. The ATSDR Toxicological Profile for Carbon Tetrachloride was published in December 1989.

Carbon tetrachloride is a clear, heavy liquid with a sweet odor. CCl_4 evaporates very easily and most CCl_4 that escapes to the environment is found as a gas in the atmosphere. CCl_4 can also be found dissolved in water. CCl_4 does not occur naturally, but is produced in large quantities to make refrigerator fluid and propellants for aerosol cans. Since refrigerants and aerosol propellants have been found to affect the earth's ozone layer, the production of these chemicals is being phased out. Consequently, the manufacture and use of CCl_4 will also tend to decline in the future.

In the past, CCl_4 was widely used as a cleaning fluid, both in industry, where it served as a degreasing agent, and in the household, where it was used to remove spots from clothing, furniture, and carpeting. Because CCl_4 does not burn, it was also used in fire extinguishers through the mid-1960s. CCl_4 was also used to fumigate grains until 1986.

Past and present releases of CCl_4 have resulted in low levels of CCl_4 throughout the environment. CCl_4 is very stable in the environment and may have an atmospheric half-life of 30 to 100 years. In ambient air concentrations of 0.1 ppb are common with somewhat higher values in cities (0.2–0.6 ppb). CCl_4 is also found in some drinking water supplies, usually at concentrations less than 0.5 ppb. CCl_4 has been found in water or soil at about 7% of the waste sites investigated under Superfund, at concentrations ranging from less than 50 ppb to over 1,000 ppb.

Most information on the health effects of CCl_4 in humans comes from cases involving short-term high-level exposures. Studies have not been performed involving long-term, low-level exposures. The major target organs following exposure to CCl_4 include the central nervous system, the liver, and the kidneys. The most immediate effects are usually on the central nervous system. Common effects include headache and dizziness, along with nausea and vomiting. In severe cases, stupor or even coma can result. These effects usually disappear within a day or two after exposure, but permanent damage to nerve cells can occur in severe cases. The liver is especially sensitive to CCl_4; in mild cases the liver becomes swollen and tender which can progress to fatty infiltration, and ultimately to necrosis and a decrease in liver function. Kidney effects can include decreased urinary production, toxic uremia, and kidney failure.

CCl_4 can affect other tissues in the body. Limited information from animal studies indicates that inhaled CCl_4 does not cause birth defects but might decrease the survival rate of new born animals. Studies in animals have also shown that CCl_4 can cause liver tumors following oral exposure.

On the basis of the available data, ATSDR has identified the following priority data needs:

Exposure

- Evaluation of existing data on concentrations of carbon tetrachloride in contaminated media at hazardous waste sites.
- Exposure levels in humans living near hazardous waste sites and other populations such as workers exposed to CCl_4.
- Candidate for registry of exposed persons.

Toxicity

- Dose response data in animals for chronic oral exposures; extended reproductive organ and nervous tissue (and demeanor) histopathological examinations should be included.
- Immunotoxicology testing via drinking water.
- Epidemiologic studies on the health effects of CCl_4.

II. Introduction: ATSDR's Substance-Specific Research Program

A. Legislative

Section 104(i)(5) of the Comprehensive Environmental Response,

Compensation, and Liability Act (CERCLA) directs the Administrator of ATSDR (in consultation with the Administrator of EPA and agencies and programs of the Public Health Service) to assess whether adequate information on the health effects of carbon tetrachloride (CCl_4) is available. Where adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a program of research designed to determine these health effects. Such program shall include, to the extent necessary to supplement existing information, but shall not be limited to—

- Laboratory and other studies to determine short, intermediate, and long-term health effects;
- Laboratory and other studies to determine organ-specific, site-specific, and system-specific acute and chronic toxicity;
- Laboratory and other studies to determine the manner in which such substances are metabolized or to otherwise develop an understanding of the biokinetics of such substances; and
- Where there is a possibility of obtaining human data, the collection of such information.

Section 104(i)(5)(C): In the development and implementation of the research program ATSDR is required to coordinate with EPA and NTP to avoid duplication of research being conducted in other programs and under other authorities.

Section 104(i)(5)(D): It is the sense of Congress that the costs for conducting this research program be borne by private industry, either under the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), or cost recovery under CERCLA.

B. Impact on Public Health

The major purpose of this research program is to supplement the substance-specific informational needs of the public and the scientific community. More specifically for ATSDR, this program will supply necessary information for conducting Health Assessments as more fully described in the ATSDR Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles (54 FR 37618) (henceforth referred to as the ATSDR Decision Guide). Experience from ATSDR Health Assessments indicates the need, for select substances, for additional information on both exposure and toxicity in order for the Agency to more completely assess human health effects. Exposure data collected from this substance-specific research effort will complement data being collected on a site-specific basis by the ATSDR Division of Health Studies and Division of Health Assessment and Consultation. More specifically, the exposure data will be used by the Agency to assist in identifying populations in need of follow-up exposure or health outcome studies. Regarding substance toxicity, the data collected will be used to characterize the toxicity of the substance for use by the public and the scientific community; for ATSDR, the data are necessary and essential to improve the design and conduct of follow-up health studies.

C. Procedures

Section 104(i)(2) of CERCLA, as amended, requires that ATSDR (1) with EPA develop a list of hazardous substances found at NPL sites (in order of priority), (2) prepare toxicological profiles of those substances, and (3) assure the initiation of a research program to fill identified data needs associated with the substances. To date, ATSDR has listed 250 hazardous substances and prepared 110 toxicological profiles, in draft or final, covering 130 substances.

The first step in implementing the ATSDR substance-specific applied research program for carbon tetrachloride was with the determination of the data needs for CCl_4 in the ATSDR Toxicological Profile for Carbon Tetrachloride (ATSDR 1989). These data needs, determined as a subset of all information gaps on CCl_4, were reviewed by scientists from the ATSDR, NTP, EPA, and the Centers for Disease Control; peer reviewed by an external review panel on two occasions; and made available for public comment. All comments received by ATSDR on the identification of data needs for CCl_4 were addressed prior to the finalization of the toxicological profile; thus ATSDR believes that these are the data needs for CCl_4 necessary to perform health assessments.

The purpose of this paper is to take the data needs identified in the Toxicological Profile for Carbon Tetrachloride and subject them to further scientific evaluation leading to priorities and ultimately to ATSDR's substance-specific research agenda. In order to effect this step, ATSDR developed and presented a logical scientific approach to priority setting in its Decision Guide.

Briefly, data needs are categorized as exposure or toxicity and are then subcategorized across three levels (Tables 1 and 2). Level I research is defined as a base set of exposure and toxicity information for identifying basic characteristics of each substance. Level II research is conducted to confirm the toxicity and exposure indicated by Level I data; and Level III is defined as research to improve the application to humans of the results of Level II research.

The Decision Guide recognized three general principles for setting priorities:

- Not all information gaps identified in toxicological profiles are data needs.
- All data needs are not of the same priority.
- Substances should be considered individually but may be grouped because of structural similarity or other relevant factors.

Other considerations spelled out in the Decision Guide include:

- All levels of data should be considered in selecting priority data needs.
- Level I gaps are not automatically in the priority grouping. In general, Level I data have priority when there are no higher level data for the same category, and when data are insufficient to make higher level priority testing decisions. For example, priority would generally not be assigned multigeneration animal studies (Level II) if an adequate subchronic study (Level I) had not been conducted that evaluated reproductive organ histopathology.
- Priority for either exposure or toxicity data requires thorough evaluation of research needs in other areas to help achieve a balanced research program for each substance.

The Decision Guide listed the following 8 tenets for determining research priorities.

- Development and/or confirmation of appropriate analytical methods.
- Determination of environmental and human exposure levels when analytical methods are available.
- Bioavailability studies for substances with known significant toxicity and exposure.
- Studies available to characterize target organs and dose response.
- Disposition studies and comparative physiological-based pharmacokinetics studies when a toxic endpoint has been determined and differences in species response have been noted.
- Mechanistic studies on substances with significant toxicity and substantial human exposure.
- Investigation of methods for mitigation of toxicity for substances where enough is known about mode of action to guide research.

• Epidemiologic studies designed to link human disease with a substance of known significant toxicity.

These last three "prioritizing" tenets address Level III research. When Level III research is identified as priority, it will not be the practice of ATSDR to develop in detail the methodologies for successful fulfillment of the data needs. As there are no standard "testing guidelines" for Level III research, it is anticipated that considerable discussion is likely to take place by parties interested in conducting this research. Thus, ATSDR will go no further than to announce that it believes that the accumulation of Level III research is appropriate and a priority at this time and state the reasons why it believes this to be so.

D. Selection Criteria

ATSDR prepares toxicological profiles on substances that are most commonly found at facilities on the NPL and which, in its sole discretion, pose the most significant threat to human health due to their known or suspected toxicity and potential for human exposure. Support documentation for inclusion of carbon tetrachloride on this list can be found as part of the ATSDR Administrative Record (Docket #1). Briefly, the rationale is as follows.

I. Frequency of Occurrence

Finding: Carbon tetrachloride appeared in the ATSDR first priority list of 100 hazardous substances published in the **Federal Register** (52 FR 12866) on April 17, 1987. It was selected from a list of 717 hazardous substances currently identified under section 102 of CERCLA.

CCl_4 has been detected in at least 134 of 1177 NPL hazardous waste sites in the United States (MIS 1990). Exposure to CCl_4 at these sites may occur by contacting contaminated air, water, soil or sediment. ATSDR is presently evaluating the extent of media-specific contamination at these and other sites.

2. Potential for Human Exposure

Finding: ATSDR has determined that there has been significant past exposure and that the potential exists for current and future human exposure to carbon tetrachloride via all routes of exposure.

The following is a brief summary of the potential for human exposure to CCl_4. Please refer to the ATSDR Toxicological Profile for Carbon Tetrachloride, "Ch.5 Potential for Human Exposure" (ATSDR 1989), for a more detailed discussion of available information.

The chlorinated, aliphatic hydrocarbon carbon tetrachloride is a clear, heavy liquid used in the manufacture of refrigerants and propellants for aerosol cans. In the early part of this century, CCl_4 was taken by mouth as a treatment for intestinal worms and was also used briefly as an anesthetic. Because CCl_4 is a powerful solvent, it has been widely used as a cleaning fluid in the home and as a degreaser in industry. Because it is nonflammable, it was also used in fire extinguishers. Until recently, it was used as a solvent in some household products, and as a fumigant to kill insects in grain. Until 1986 the largest source of release occurred during CCl_4 production or during the use of CCl_4 in the manufacture of chlorofluorocarbons and other chemical products.

This simple aliphatic halocarbon is an important substance for research because of its widespread environmental contamination. Carbon tetrachloride is a stable chemical that is degraded very slowly, so there has been a gradual accumulation of CCl_4 in the environment as a consequence of releases from human activities. The total release of CCl_4 into the environment from point sources was reported to be 3,811,851 pounds in 1988 and 4,690,926 pounds in 1987 (TRI 1990). Continued monitoring studies by Simmonds et al. (1988) reveal that global atmospheric levels of CCl_4 have been steadily increasing by about 1.3% per year, reaching 0.22 to 0.14 ppb by 1985. Average values for suburban and urban areas were 0.19 ppb, and 0.59 ppb near point sources of CCl_4 (Brodzinski and Singh 1983). Recent studies have revealed that CCl_4 is also a common contaminant of indoor air. Typical concentrations in homes in several U.S. cities were about 0.16 ppb, with some values up to 1.4 ppb (Wallace 1986). Results of six major government surveys revealed that about 99% of all groundwater supplies and about 95% of all surface water supplies in this country are contaminated with CCl_4 (Letkiewicz et al. 1983). In the National Organics Reconnaissance Survey, the EPA found CCl_4 levels of less than 3 ppb in drinking water in 80 cities (Symons et al. 1975). The more recent National Organics Monitoring Survey of 113 public drinking water systems found CCl_4 in the range of 2.4–6.4 ppb in 10% of the samples surveyed (EPA 1980). However, at NPL sites, the extent of contamination of the environmental pathways is not yet known, nor is the potential for human contact to these pathways. Results from human and animal studies indicate that CCl_4 is readily absorbed following all routes of exposure.

The National Occupational Exposure Survey (NOES) conducted by NIOSH indicated that 104,172 workers, including 20,697 women, were potentially exposed to carbon tetrachloride in the workplace during the period of 1980–1983 (NIOSH 1991). However, no information was available on the frequency, level, or duration of exposure to CCl_4.

3. Toxicity

Finding: ATSDR finds that short, intermediate, and long-term health effects can result from inhalation, ingestion, and dermal contact of CCl_4 liquid or vapor. Target organs or systems known to be affected include the liver, kidney, reproductive, and nervous systems.

The following is a brief summary of the toxicology of carbon tetrachloride. Please refer to the ATSDR Toxicological Profile for Carbon Tetrachloride, "Ch.2 Health Effects" (ATSDR 1989), for a more detailed discussion of available information.

The toxicology of CCl_4 has been extensively investigated in animals, both by oral and inhalation exposure. Most toxicity studies have focused on hepatotoxicity, renal toxicity, and central nervous system depression. Several studies have examined the neurologic, developmental, and reproductive effects of CCl_4. There are numerous studies on the carcinogenic effects of CCl_4 in animals following oral exposure. However, many of these studies were performed before the establishment of Good Laboratory Practices.

Drugs and other chemicals that increase the metabolism of CCl_4 can increase the toxicity of CCl_4. Thus, individuals who are moderate to heavy drinkers, as well as those exposed to isopropanol are at greatly increased risk of liver and/or kidney injury following exposure to CCl_4. In addition, exposure to trichloroethylene, other haloalkanes, primary, secondary and tertiary alcohols and their ketones have been identified as potentiating the toxicity of CCl_4.

Other conditions such as poor nutritional status, preexisting liver or kidney disease, diabetes, genetically-based high mixed function oxidase (MFO) activity and personal habits (smoking) may predispose an individual to CCl_4 toxicity.

III. Identification of Data Needs

In evaluating the exposure and testing needs for CCl_4, ATSDR considered all available published and unpublished information that has been peer reviewed. From its evaluation of these data, ATSDR is recommending the conduct of specific research or testing.

A. Exposure Data Needs (Table 1)

Three of the eight "prioritizing" tenets presented in the Decision Guide directly address exposure data needs.

- Development and/or confirmation of appropriate analytical methods.
- Determination of environmental and human exposure levels when analytical methods are available.
- Bioavailability studies for substances of known significant toxicity and exposure.

The progressive accumulation of exposure information begins with the development of suitable analytical methods for analysis of the compound in all relevant biological and environmental media, followed by confirmation of exposure information, prior to the conduct of any Level III research. However, in order to know what analytes are available for monitoring, some basic environmental fate information is generally required and becomes a priority if it is lacking. Bioavailability and food chain bioaccumulation studies are appropriately placed in Level II, and should be undertaken after analytical methods are developed and confirmation of the substance is achieved in numerous hazardous waste sites and media.

1. Levels I & II Data Needs

a. *Analytical. Purpose:* To determine if available methods are adequate for detecting and quantifying levels of carbon tetrachloride in environmental and biological matrices. The methods should be sufficiently specific and sensitive to measure (1) background levels in the environment and the population; and (2) levels at which biological effects might occur.

Finding: A data need has been identified. Generally, adequate methods are available for analysis in air (NIOSH 1984), water (EPA 1982), soil (EPA 1986), solid waste, and for most biological media (Peoples et al. 1979; Suitheimer et al. 1982). These methods for air and water appear to be sufficiently sensitive to measure levels in the environment that may be associated with adverse human health effects, i.e., ATSDR minimal risk levels (MRLs). However, the EPA estimated 10^{-6} cancer risk levels for CCl_4 (0.01 ppb in air and 0.3 ppb in drinking water) may present a sensitivity problem for some methods. Analytical methods exist for the measurement of the stable metabolites of CCl_4 (CO_2, CO, $CHCl_3$, CCl_3CCl_3), but none of these offer any advantages over measurement of parent CCl_4. Additionally, there is a need for standard methods to isolate CCl_4 from biological samples that are quantitative, rapid, and easily performed.

Priority Recommendation: The identified data need is not considered priority. These needs are not considered major deficiencies, and ATSDR considers that further research is not needed at this time.

b. *Physical/Chemical Properties. Purpose:* To determine whether adequate data on the chemical and physical properties of carbon tetrachloride are available to permit estimation of its environmental fate under various conditions of release.

Finding: Physical and chemical properties (Kow, Koc, Henry's Law Constant, vapor pressure, etc.) have been well studied and reliable values for key parameters are available for use in environmental fate and transport models.

Priority Recommendation: None identified.

c. *Exposure Levels.* i. *Environmental Media. Purpose:* To determine whether adequate data are available on the levels of CCl_4 in the ambient and contaminated environments for purposes of conducting meaningful follow-up exposure and health studies.

Finding: A data need has been identified. CCl_4 has been produced and used in large volumes in the environment, home, and industry. Levels in air and water have been measured at numerous locations in the United States, and typical or average exposure levels are fairly well defined; however, concentrations of CCl_4 in contaminated environmental media at hazardous waste sites has not been well characterized.

Continued monitoring studies by Simmonds et al. (1988) reveal that global atmospheric levels of CCl_4 have been steadily increasing by about 1.3% per year, reaching 0.12 to 0.14 ppb by 1985. Average values for suburban and urban areas were 0.19 ppb, and 0.59 ppb near point sources of CCl_4 (Brodzinski and Singh 1983). Recent studies have revealed that CCl_4 is also a common contaminant of indoor air. Typical concentrations in homes in several U.S. cities were about 0.16 ppb, with some values up to 1.4 ppb (Wallace 1986). Results of six major government surveys revealed that about 99% of all groundwater supplies and about 95% of all surface water supplies in this country are contaminated with CCl_4 (Letkiewicz et al. 1983). In the National Organics Reconnaissance Survey, the EPA found CCl_4 levels of less than 3 ppb in drinking water in 80 cities (Symons et al. 1975). The more recent National Organics Monitoring Survey of 113 public drinking water systems found CCl_4 in the range of 2.4–6.4 ppb in 10% of the samples surveyed (EPA 1980). No data were located on background levels of CCl_4 in ambient soil. However, since CCl_4 is ubiquitous in air, it is likely that trace levels of CCl_4 are present in surface soils.

No information is available on air levels of CCl_4 around NPL waste sites. Carbon tetrachloride has been detected in groundwater at 5–6% of all NPL sites and other chemical waste sites being investigated under Superfund. Quantitative data are sparse, but typical values range from less than 50 to over 1000 ppb (ATSDR 1988; CLPSD 1988). Soil surveys performed at waste sites have detected CCl_4 in 2.2% of soil samples; at a mean concentration of 290 ug/kg (CLPSD 1988). Despite this small amount of information at NPL sites, the overall extent of contamination of the environmental pathways is not yet known, nor is the potential for human contact to these pathways. An effort is currently underway at ATSDR to assess the available media-specific information at the 134 NPL sites contaminated with CCl_4.

Priority Recommendation: The identified data need is considered priority. No recent data are currently available to assess the overall extent of contamination by CCl_4 at hazardous waste sites. These data are needed so that the information obtained on the levels of CCl_4 in the environment and the resulting body burden of CCl_4 can be used to assess the potential risk of developing adverse health effects in populations living in the vicinity of these waste sites. One effort is currently underway at ATSDR that will examine the extant data at the 134 NPL sites at which CCl_4 has been found. When complete, this database will include concentrations of CCl_4 in on-site and off-site media, the size of the potentially exposed population, and an indication of relevant routes of exposure. This database will be developed and evaluated before the need to collect additional media-specific data is assigned priority.

ii. *Humans. Purpose:* To determine whether adequate data are available on the levels of CCl_4 in human tissues for the general population and exposed populations for purposes of conducting meaningful follow-up exposure and health studies. ATSDR does not consider that this information can be reliably predicted from modeling and other risk assessment procedures.

Finding: There are limited studies in the literature that examined tissue levels of CCl_4 following generally acute exposures. Stewart et al. (1961) and

Stewart and Dodd (1964) reported no apparent effects in volunteers (exposed via inhalation and dermal contact) whose expired air levels of CCl_4 were 3 ppm or lower.

Distinct central nervous system depression was detected in one worker whose expired air level was 9.5 ppm (Stewart et al. 1965). Ruprah et al. (1985) measured the levels of CCl_4 in the blood of 16 persons who were admitted to the hospital with symptoms of acute CCl_4 poisoning. Typical blood concentrations ranged from 1–10 mg/L.

There are no similar studies reported that examined tissue levels of CCl_4 following repeated or prolonged exposures. The U.S. Department of Health and Human Services is sponsoring an on-going study (the National Health and Nutrition Examination Survey, NHANES III) which will provide data on levels of CCl_4 in blood and urine of humans at numerous locations across the country. Data on CCl_4 levels in human fat is continuing to be collected under the National Human Adipose Tissue Survey (NHATS) sponsored by EPA. However, no actual human exposure level data from individuals living near hazardous waste sites (general population) or workers is anticipated to be collected.

Priority Recommendation: The identified data need is considered priority. Building a sound basic data foundation for higher level environmental research via the decision guide requires the determination of human exposure levels on CCl_4. Although referent tissue levels are currently being determined in on-going studies (NHANES III), no actual human exposure level data from individuals living near hazardous waste sites are anticipated to be collected. Information on exposure levels in humans is necessary to better define exposure estimates in the general population and the workforce, and to examine the relationship between levels of CCl_4 in the environment, human tissue levels, and the subsequent development of health effects. Thus, collection of this data should be concurrent with the acquisition of data from the NHANES III study.

One effort is currently underway at ATSDR that will examine the extant data at the 134 NPL sites at which CCl_4 has been found. When complete this database will include concentrations of CCl_4 in on-site and off-site media, the size of the potentially exposed population, and an indication of relevant routes of exposure. This database will not, however, supply information on the levels of CCl_4 (or its metabolites) in the tissues of individuals living near hazardous waste sites or other exposed populations such as workers.

d. *Environmental fate. Purpose:* To determine whether the available data are adequate to estimate exposure to CCl_4 under various conditions of environmental release for purposes of planning and conducting meaningful follow-up exposure and health studies.

Finding: A data need has been identified. The environmental fate of CCl_4 has been well studied, however additional information is needed on atmospheric lifetime and flux rates from surface waters. The available data on CCl_4 are adequate to conclude that one main fate process is volatilization followed by photodecomposition; however, there is considerable uncertainty in available estimates of atmospheric lifetime, but most values range from 30 to 100 years (Molina and Rowland 1974; Singh et al. 1979; Simmonds et al. 1983, 1988). Although only a small fraction of environmental CCl_4 is thought to exist in surface waters, the possibility exists that hydrolysis, bioaccumulation or adsorption, while slow, could compete with the slow photodecomposition occurring in the atmosphere. Thus, additional studies on flux rates into and out of surface water, as well as refined quantitative estimates of aquatic fate processes are necessary to predict human exposure potential to CCl_4 in the environment. The calculated half-life for hydrolysis of CCl_4 in water is 7,000 years at a concentration of 1 ppm (Mabey and Mill 1978). No data are available on the expected half-life of CCl_4 in soil.

Priority Recommendation: The identified data needs are not considered priority. The major release medium for CCl_4 is to the atmosphere where its fate and stability have been fairly well characterized. Additionally, a major route of concern at Superfund sites is exposure via groundwater where information is available to conclude that CCl_4 will generally persist for several hundred years. The need to conduct the additional environmental fate studies identified, while still data needs, are not assigned priority at this time because of the advanced stage of knowledge on exposure to CCl_4 and the importance of characterizing the potentially large population currently exposed to CCl_4.

e. *Bioavailability and Bioaccumulation Potential. Purpose:* To determine whether adequate data are available to predict the potential of CCl_4 to be taken up by individuals exposed via contaminated air, soil, water, and the food chain for purposes of conducting meaningful follow-up exposure and health studies.

Finding: A data need has been identified. No studies were located regarding bioavailability of CCl_4 from various environmental media. The primary routes of exposure to CCl_4 at Superfund sites are likely to be either through ingestion of contaminated water or inhalation of contaminated air. The absorption of CCl_4 through these pathways is likely to be high and to approximate that seen under laboratory test conditions where neat CCl_4 is tested (30–60%). Although CCl_4 is lipophilic and is moderately adsorbed to soils and sediments, it would not be expected that this would significantly restrict its bioavailability. However, limited data indicate that both the noncarcinogenic and carcinogenic effects of CCl_4 given by the oral route depend, in part, on whether exposure occurs in an aqueous or an oil vehicle. This indicates that equal doses of CCl_4 in fish, soil, sediment, water and air may not be equally toxic in humans. Thus, information on the bioavailability of CCl_4 is required to evaluate the most important routes of exposure for populations living in the vicinity of hazardous waste sites, and to identify populations most likely to be at risk of exposure and development of health effects. Although CCl_4 is relatively lipophilic, there is little tendency for this compound to bioaccumulate in aquatic or marine organisms.

Priority Recommendation: The identified data need is not considered priority. The need to conduct additional studies to address the uncertainties stated above, while still data needs, are not assigned priority at this time because of the advanced stage of knowledge on exposure to CCl_4 and the importance of characterizing the potentially large population currently exposed to CCl_4. Additionally, if populations are identified where prominent routes of exposure to CCl_4 are via other routes, e.g., fish and soil, these bioavailability studies may become priority.

2. Level III Data Needs

a. *Registries of exposed persons. Purpose:* To evaluate and determine whether known populations exist that may have high exposures to carbon tetrachloride. The ATSDR Division of Health Studies will be informed of all candidate substances for consideration of future registries.

Finding: A data need has been identified. Carbon tetrachloride has been found in at least 134 NPL hazardous waste sites. At this time no formal registries exist that identify individuals known to have been

exposed to CCl_4. The development of an exposure registry would provide an important reference tool for evaluating levels and frequencies of exposure to CCl_4. It would also facilitate the conduct of epidemiological or health studies to assess any increased incidence of chronic diseases or late-developing effects such as cancer. An effort is currently underway at ATSDR to identify those sites where known human exposure to site contaminants has occurred. From those sites identified, ATSDR can determine which sites list CCl_4 as a contaminant and the size of the potentially exposed population.

Priority Recommendation: The identified data need is considered priority. This is justified based upon the large number of sites where CCl_4 has been found and the advanced stage of knowledge on the potential exposure and toxicity of CCl_4. This recommendation will be provided to the ATSDR Division of Health Studies who will judge the extant information on CCl_4 against its criteria for initiating an exposure registry.

B. Toxicity Data Needs (Table 2)

The five remaining "prioritizing" tenets presented in the Decision Guide address toxicity data needs.

- Studies available for all toxicological profile substances to characterize target organs and dose response.
- Disposition studies and comparative physiologically-based pharmacokinetics when a toxic endpoint has been determined and differences in species response have been noted.
- Mechanistic studies on substances with significant toxicity and substantial human exposure.
- Investigation of methods for mitigation of toxicity for substances where enough is known about mode of action to guide research.
- Epidemiologic studies that will provide a direct answer on human disease for a substance of known significant toxicity.

The following is a brief summary of the toxicity data needs for carbon tetrachloride. Please refer to the ATSDR Toxicological Profile for Carbon Tetrachloride" Chapter 2 on Health Effects" (ATSDR 1989), for a more detailed discussion of available information. Generally, ATSDR believes that the most relevant route of human exposure to carbon tetrachloride at waste sites is ingestion of contaminated media; thus, ATSDR believes that the proposed toxicity studies should be conducted via oral exposure, preferably drinking water. However, ATSDR is aware that the solubility of CCl_4 may present a design problem for some proposed studies. Toward this end, ATSDR notes that the effects of oral dosing vehicles on CCl_4 toxicity was recently (TAP; 102; pp 34–49) studied and it was found that corn oil reduced the acute hepatotoxic effects by delaying absorption. The use of aqueous Emulphor was determined the most appropriate vehicle for these studies. Additionally, animal testing should be conducted on the species with metabolism most similar to man or the most sensitive species.

Levels I & II Data Needs

ATSDR is mandated to determine the levels of significant human exposure for each substance and the associated acute, subacute, and chronic health effects. In order to accomplish this goal, ATSDR determines MRLs which are defined as estimates of daily human exposure to a chemical that are likely to be without appreciable risk of deleterious effects over a specified duration. In order to derive MRLs for acute, intermediate, and chronic exposure durations, ATSDR evaluates the substance-specific database to identify studies of the appropriate route and duration of exposure.

At this time, ATSDR does not extrapolate data across routes or durations of exposure. The scientific basis for this practice has recently been prepared and presented to the ATSDR Board of Scientific Counselors. However, ATSDR does acknowledge that such extrapolations may be done on a substance by substance basis after toxicokinetics information has been collected. Thus, in order to derive acute MRLs, ATSDR evaluates studies of less than 14 days durations that identify the target organs and levels of exposure associated with these effects. Similar studies are identified for intermediate and chronic duration exposures.

Currently, as reflected in the Decision Guide, it is the practice of ATSDR to assign priority to identified data needs for acute/intermediate (Level I) studies by the most relevant route of exposure at Superfund sites. Regarding the need to conduct studies by other routes of exposure, ATSDR will generally first require toxicokinetic studies for the three routes of exposure to determine the need for the additional route-specific information. Regarding chronic studies, ATSDR acknowledges that appropriately conducted 90-day studies can generally predict the target organs for chronic exposure, but may fall short in accurately predicting the levels of exposure associated with these effects. Although, ATSDR acknowledges this fact, it will generally await the results of prechronic (14- & 90-day) and toxicokinetic studies prior to assigning priority to chronic toxicity studies. Note: Chronic toxicity studies may be separated from bioassays and require an exposure duration of one year.

a. *Acute-Duration Exposure. Purpose:* To determine whether adequate data exist to identify target organs and levels of exposure which present a significant risk to human health of acute health effects.

Finding: A data need has not been identified. A large number of studies are available regarding the effects of single exposures to CCl_4. Collectively, these studies indicate that the liver, kidneys, and nervous system are the major target organs/systems following CCl_4 exposure; although many of these involved exposure to only one dose level, and threshold doses were not defined. However, the data were considered acceptable to derive ATSDR Minimal Risk Levels (MRLs) for acute inhalation (Stewart et al. 1961) and oral exposures (Bruckner et al. 1986). Higher confidence in the inhalation MRL would require additional studies in animals involving a range of exposure concentrations and employing sensitive histological and biochemical measurements of injury to the liver, kidney, and immune systems. The limited data that exist following dermal exposure to CCl_4 in humans and animals indicate that, other than direct dermal irritation, the target organs affected are similar to those following oral and inhalation exposure.

Priority Recommendation: None identified.

b. *Intermediate-Duration Exposure. Purpose:* To determine whether adequate data exist to identify target organs and levels of exposure which present a significant risk to human health of subacute health effects.

Finding: A data need to conduct intermediate-duration dermal dose studies has been identified. Inhalation and oral studies are available that indicate that the liver is the target organ following intermediate duration exposure to CCl_4; and ATSDR MRLs have been derived from this database (Adams et al. 1952; Bruckner et al. 1986). Although it is likely that target organs following dermal contact would be similar to those following inhalation or oral exposure, studies in animals dermally exposed to CCl_4 are necessary to determine no-effect and threshold levels for toxicity.

Priority Recommendation: The data need is not considered priority. The lack of dermal data is not considered a priority data need at this time because

(1) waste sites exposures via this route are tertiary compared to oral and inhalation; (2) dermal absorption of CCl_4 is relatively modest compared to oral or inhalation; and (3) there are no data to indicate that target organs following dermal exposure would differ from oral and inhalation.

c. Chronic-Duration Exposure. i. *Toxicity Assessment. Purpose:* To determine whether adequate data exist to identify target organs and levels of exposure which present a significant risk to human health of chronic health effects.

Finding: A data need has been identified. No dermal data or reliable inhalation data were available for assessing target organs and threshold effects following chronic exposure to CCl_4; thus no inhalation ATSDR MRL has been determined. One two-year oral study in rats was available that established no-effects levels for systemic (liver and kidney) and reproductive toxicity (Alumot 1976). However, this study was not adequate to determine an ATSDR MRL because (1) no evidence for any effects on target organs were noted, and (2) the no-observed-adverse-effect-level (15 mg/kg/d) for this chronic duration study is higher than intermediate duration lowest-observed-adverse-effect-levels reported in two other studies (Bruckner et al. 1986, 10 mg/kg/d; Condie et al. 1986, 12 mg/kg/d).

Priority Recommendation: The identified data need to conduct a chronic oral study is considered priority. Although several studies are available, or currently ongoing, that can be used to predict the chronic toxicity of CCl_4, these studies will not define the levels of CCl_4 in drinking water associated with health effects. Thus, ATSDR believes a chronic toxicity study of CCl_4 in drinking water is a priority data need. Oral studies should be done in drinking water rather than gavage in corn oil. A two-year inhalation study on carbon tetrachloride was reportedly recently conducted by Yoshikawa but has not been submitted to ATSDR. The lack of dermal data is not considered a priority data need at this time because (1) waste sites exposures via this route are tertiary compared to oral and inhalation; (2) dermal absorption of CCl_4 is relatively modest compared to oral or inhalation; and (3) there are no data to indicate that target organs following dermal exposure would differ from oral and inhalation.

ii. *Cancer Assessment. Purpose:* To determine whether populations potentially exposed to carbon tetrachloride are at an increased risk for developing cancer for purposes of conducting meaningful follow-up exposure and health studies. Similar to toxicity endpoint assessment, when bioassays are indicated because of the potential for substantial exposure and the lack of information on carcinogenicity, ATSDR will generally only assign priority to a bioassay conducted via the most relevant route of human exposure at Superfund sites. Comparative toxicokinetic information across routes as previously discussed will be assigned priority and conducted before assigning priority to any additional routes of exposure. In cases where the assessment of chronic toxicity and carcinogenicity can be combined, they will.

Finding: A data need has not been identified. The ATSDR Toxicological Profile for CCl_4 concludes that there is ample evidence that oral (Eschenbrenner and Miller 1946; Della Porta et al. 1961; NCI 1976) and parenteral exposure to CCl_4 causes increased tumor frequency in animals. Similar conclusions have been reached by the International Agency for Research on Cancer (IARC V.20, 1979) and the NTP (sufficient evidence for the carcinogenicity of CCl_4 in experimental animals; "may reasonably be anticipated to be a carcinogen," NTP. 1989). Based on the similarity of the hepatotoxic effects of CCl_4 by oral, parenteral, and inhalation exposure, it is reasonable to conclude that it would cause tumors by the inhalation route also; furthermore, there is an on-going cancer study in Japan of rats and mice exposed by inhalation.

Priority Recommendation: None identified.

d. *Genotoxicity. Purpose:* To evaluate the mechanism of CCl_4-induced toxicity for purposes of future mitigation activities. Generally, priority is assigned genotoxicity studies if information is lacking to assess the genotoxic potential of this substance both in vivo (mouse micronucleus) and in vitro (Ames Salmonella). This is particularly true if there are human data to suggest that the substance may act by a genotoxic mechanism to cause cancer, reproductive toxicity, etc. or there exists "structural alerts" that suggest that the substance may be genotoxic. Additional studies will not be assigned priority simply to confirm or refute an equivocal database without justification.

Finding: A data need has not been identified. Although metabolism-dependent binding of CCl_4 to DNA and nuclear proteins has been demonstrated both *in vivo* and *in vitro* (Rocchi et al. 1973; Diaz Gomez and Castro 1980 a,b), most studies of the mutagenic potential of CCl_4 have been negative (Barber et al. 1981; McCann et al. 1975; Simmon et al. 1977; Uehleke et al. 1977; Dean and Hodson-Walker 1979). No additional Level I or II studies are needed at this time, however further studies designed to evaluate carcinogenic mechanisms would be necessary to establish whether tumor induction in animals is via genotoxicity. Furthermore, several ongoing mechanistic studies have been identified that are examining subcellular targets of CCl_4 toxicity. The results from these studies should be examined prior to the initiation of additional research.

Priority Recommendation: None identified.

e. *Reproductive toxicity. Purpose:* To determine whether populations potentially exposed to carbon tetrachloride are at an increased risk for developing reproductive effects for purposes of conducting meaningful follow-up exposure and health studies. The ATSDR places importance on the acquisition of reproductive toxicity data in its desire to consider the needs of susceptible populations. Additionally, it is desirable to have information on reproductive toxicity prior to the development of MRLs to ensure that target organs have been adequately evaluated.

Generally, when considering the need to assign priority, ATSDR will, in the absence of all information on this endpoint, assign priority to the conduct of 90-day studies with special emphasis on reproductive organ pathology. If (1) any indication is found in these studies that the reproductive system of either male or female animals is a target organ of substance exposure; or (2) there have been human anecdotal reports of reproductive effects following substance exposure; or (3) there are structurally similar compounds that affect reproduction, then ATSDR will consider assigning priority to multigeneration animal studies. As before, priority will be assigned to studies conducted by the most relevant route of human exposure at Superfund sites; comparative toxicokinetic studies will be performed and evaluated prior to assigning priority to studies conducted via additional routes of exposure.

Finding: A data need has been identified. No studies were located regarding the effects of CCl_4 on reproduction in humans. In animals, Smyth et al. (1936) did detect a decrease in fertility in rats exposed to CCl_4 by inhalation for three generations, but no effect on reproduction was detected by Alumot et al. (1976) in rats exposed in feed for two years (five generations). Adams et al. (1952) noted marked degeneration of testicular germinal

epithelium in rats exposed repeatedly to 200 ppm or higher in air. These data are suggestive that CCl_4 may affect reproduction, but are not extensive enough to draw firm conclusions. Multigeneration studies via drinking water using modern parameters are necessary to properly evaluate the relevance of this endpoint via the primary route of exposure at waste sites.

Priority Recommendation: The identified data need to conduct a multigeneration animal study via drinking water is not considered priority. The extant toxicology database does not indicate that the reproductive system is particularly sensitive to the effects of CCl_4. The Alumot et al. (1976) study, although not conducted via drinking water, was conducted at or near the maximum tolerated dose throughout its two-year duration with no associated reproductive toxicity noted. However, consideration should be given to an extensive examination of the reproductive tract of animals exposed via drinking water in future chronic toxicology testing. Results from these studies may influence a future decision on priority testing needs for CCl_4. Additionally, future epidemiologic studies should give special emphasis to evaluation of this endpoint.

f. *Developmental toxicity. Purpose:* To determine whether populations potentially exposed to carbon tetrachloride are at an increased risk for developing developmental effects for purposes of conducting meaningful follow-up exposure and health studies. Similar to reproductive toxicity assessment, the Agency places importance on the assessment of developmental toxicity data in its desire to consider the needs of susceptible populations.

In the absence of any reproductive or teratologic information, ATSDR will consider proposals to simultaneously acquire reproductive and teratological information. Additionally, ATSDR acknowledges that there will be some circumstances that require that separate conduct of classical teratology studies; these studies are generally assigned priority after the conduct of 90-day studies that assess reproductive organ pathology, the consideration of data generated on structurally similar compounds, or the evidence from human anecdotal reports. As for reproductive toxicity, priority will be assigned to studies conducted by the most relevant route of human exposure at Superfund sites; comparative toxicokinetic studies will be performed and evaluated before assigning priority to the conduct of studies via additional routes of exposure.

Finding: A data need to conduct additional developmental toxicity studies in animals has been identified. Limited data suggest that CCl_4 has low developmental toxicity in animals which may reflect the fact that the fetus of most animals lack the enzymes needed for activation of CCl_4. However, this may not apply to humans where drug metabolizing activity develops at an earlier stage. No teratogenic effects were observed in rats exposed to CCl_4 either by inhalation (Gilman 1971; Schwetz et al. 1974) or the oral route (Wilson 1954), except at doses that produced clear maternal toxicity. In the Wilson (1954) study, ingestion of CCl_4 at doses of 1400 mg/kg/d during gestation caused maternal toxicity and total resorption of fetuses in some animals, but no teratogenic or other adverse effects were apparent in surviving litters. Additional developmental toxicity studies in mammalian species are necessary to address the issue of species relevance.

Priority Recommendation: The identified data need to conduct additional animal developmental toxicity studies is not considered priority. This conclusion should be re-examined in the future, especially in light of future decisions to conduct a multigeneration animal study. Of priority, however, are additional studies that examine the potential for CCl_4 to affect development in humans and full assessment of this endpoint should be considered in future epidemiological studies.

g. *Immunotoxicity. Purpose:* To evaluate the mechanism of CCl_4-induced toxicity for purposes of defining target organs and future mitigation activities. There is increasing evidence to suggest that the immune system may be a susceptible target organ for many environmental contaminants. In the absence of any information on the immune system as a target organ, priority will be assigned evaluation of the immune system (lymphoid tissue, blood components) as an endpoint in 90-day studies (Level I) before assigning priority to an immunotoxicology battery as recently defined by the NTP. For those substances that either (1) show evidence of immune system effects in 90-day studies, (2) have human anecdotal data to suggest that the immune system may be affected, or (3) are structurally similar to known immunotoxicants, an immunotoxicology battery of tests will be assigned priority.

Finding: A data need has been identified to examine the immunotoxic potential of CCl_4 administered via drinking water. A number of reports (Tajima et al. 1985; Kaminski et al. 1985) indicate that parenteral exposure to CCl_4 in animals affects the immune system. More recently, Kaminski et al. (1990) examined the role of metabolism in CCl_4-mediated immunosuppression. In this study 30-day intraperitoneal administration of CCl_4 at doses as low as 25 mg/kg resulted in significant inhibition of T-dependent antibody responses. Additionally, there are suggestive data in humans (Taylor 1925 McGuire 1932) to indicate that CCl_4 may cause a hypersensitization reaction following dermal exposure. Studies in animals following oral, inhalation, or dermal exposure are necessary to evaluate the relevance of this endpoint for human exposure.

Priority Recommendation: The identified data need is considered priority. Based on the suggestive information in humans and the limited data in animals that suggest that CCl_4 may affect the immune system, Tier I testing to assess CCl_4-induced immunotoxicity, as recently defined by the NTP (Luster et al. 1988), should be included in future subchronic or chronic toxicity testing (via drinking water). The parameters that should be measured include immunopathology, humoral-mediated immunity, cell-mediated immunity, and nonspecific immunity. Future epidemiologic studies should also place emphasis on evaluation of this endpoint.

h. *Neurotoxicity. Purpose:* To evaluate the mechanism of CCl_4-induced toxicity for purposes of defining target organs and future mitigation activities. Similar to immunotoxicity, there is a growing body of data to suggest that the nervous system is a very sensitive target organ for many environmental chemicals. In the absence of any information on the nervous system as a target organ, priority will be assigned evaluation of the nervous system as an endpoint in 90-day studies (Level I) before assigning priority to a neurotoxicology battery. Additionally, it may be possible to assign priority to evaluation of demeanor in 90-day studies along with neuropathology. For those substances that either (1) show evidence of nervous system effects in 90-day studies, (2) have human anecdotal data to suggest that the nervous system may be affected, or (3) are structurally similar to known neurotoxicants, a neurotoxicology battery of tests will be assigned priority.

Finding: A data need has been identified. Several single-dose human reports are available that indicate that

the central nervous system is a target tissue for CCl_4 following oral exposure. No oral studies in animals were available that examined this endpoint. Additional studies are necessary to define dose-dependency following longer-term exposures and to determine whether these effects are primary or secondary to effects on the liver and kidneys. Also of concern are the scattered reports that exposure to CCl_4 causes focal injury and degeneration of nerve tissue.

Priority Recommendation: The identified data need to conduct subchronic/chronic dose-dependency studies is considered priority. Consideration should be given to assessment of neurological endpoints via drinking water exposure in future chronic toxicology testing. Additionally, several ongoing mechanistic studies have been identified that are examining cellular and subcellular targets of CCl_4 toxicity. The results from these studies should also be examined prior to the initiation of additional research on the mechanism of neurotoxicity.

i. *Toxicokinetics. Purpose:* To evaluate the disposition of carbon tetrachloride across species and routes of exposure for purposes of elucidating target organs and mechanisms of toxicity, and to assess the need to conduct studies by other than the primary route of exposure.

Finding: A data need has been identified. Although metabolic pathways and mechanisms of hepatotoxicity of CCl_4 have been the subject of many studies in animals and *in vitro,* there are apparently no data on human metabolism of CCl_4. Comparative toxicokinetic studies, or actual disposition data from either human tissues or *in vivo* exposures, are necessary to predict how man will handle exposure to CCl_4.

Priority Recommendation: The identified data need is not considered priority. The ATSDR Toxicological Profile for Carbon Tetrachloride identifies several on-going toxicokinetic studies (ATSDR 1989, Table 2–6). The results of these studies need to be evaluated prior to the initiation of further toxicokinetic research.

2. Level III Data Needs

a. *Epidemiology Studies. Purpose:* To evaluate the extant epidemiologic database and to propose the conduct of additional studies that may lead to cause and effect findings. The ATSDR Division of Health Studies will be informed of all candidate substances.

Finding: A data need has been identified. Epidemiological studies on the health effects of CCl_4 are sparse, being limited to mostly observations of the effects of intermittent workplace exposure on the central nervous system, hepatic, and renal function in relatively small groups of workers. While these studies contribute to an understanding of the acute and subacute health effects of CCl_4, studies are necessary on humans living in the vicinity of hazardous waste sites contaminated with CCl_4 who may be exposed through unique pathways. Results from such exposure studies on waste site populations should be assessed prior to the initiation of health effects studies.

Priority Recommendation: The identified data need is considered priority. As waste site populations are identified with potentially significant exposures to CCl_4 (CCl_4 levels in the environment above ATSDR Environmental Media Evaluation Guides or other EPA ARARs), pilot exposure studies should be initiated. Results from these studies should be evaluated prior to the initiation of health effects studies. Additionally, in order to assess the toxicity of CCl_4 in humans, if either worker or general populations with potentially significant exposures can be confirmed, health effects studies should be undertaken with special emphasis placed upon evaluation of systemic toxicity (including immunotoxicity and neurotoxicity), carcinogenicity, and reproductive/developmental toxicity. These studies are justified based upon the potentially large numbers of individuals currently or previously exposed at waste sites, and past and present exposures of workers and the general population.

b. *Mechanism of toxic action. Purpose:* To evaluate the mechanism of CCl_4-induced toxicity for purposes of defining target organs and future mitigation activities.

Finding: A data need has been identified. Hepatotoxicity by carbon tetrachloride is believed to occur when it is metabolized by cytochrome P450 enzymes. The generation of the highly reactive free radical CCl_3 is thought to initiate the lipid peroxidation which ultimately leads to tissue damage. The ATSDR Toxicological Profile for Carbon Tetrachloride (ATSDR 1989, Table 2–6) identifies several studies that are currently in progress to evaluate the mechanisms of CCl_4-induced liver and kidney toxicity, but there are no studies designed that specifically address the mechanisms of nerve tissue damage (See Neurotoxicity above).

Priority Recommendation: The identified data need to evaluate the mechanism of nerve tissue damage caused by exposure to CCl_4 is not considered priority. The results of these on-going studies must be evaluated prior to the initiation of additional research in the area of mechanism of toxic action of CCl_4.

c. *Biomarkers. Purpose:* To evaluate the need to develop additional biomarkers of exposure and effect for purposes of future medical surveillance which can lead to early detection and treatment.

Finding: A data need has been identified to develop a sensitive and specific biomarker of effect for CCl_4. Sensitive methods are available for measuring low levels of CCl_4 in most biological media. Additionally, analytical methods exist for the measurement of the stable metabolites of CCl_4 (CO_2, CO, $CHCl_3$, CCl_3CCl_3), but none of these offer any advantages over measurement of parent CCl_4. Although a number of clinical and biochemical tests are available that can detect early signs of hepatic and renal injury in humans, none are specific for CCl_4-induced disease.

Priority Recommendation: The identified data need is not considered priority. The lack of a specific biomarker of effect for CCl_4 is not considered essential to conduct human studies because there is no unique disease state associated with exposure to CCl_4; and the identification of CCl_4 in tissues can be fairly diagnostic when combined with sensitive, non-specific biomarkers of hepatic, renal, or neurotoxicity. However, improvements in the sensitivity of these tests, or development of more specific and sensitive tests, may be necessary to adequately evaluate the health status of individuals exposed to low levels of CCl_4 at waste sites. These considerations will more appropriately be addressed in the future once populations have been identified with known exposure to carbon tetrachloride.

d. *Clinical methods of mitigating toxicity. Purpose:* To determine whether any efforts are currently underway to mitigate the effects of exposure to carbon tetrachloride.

Finding: A data need has been identified. The target organs for CCl_4-induced toxicity have been fairly well studied and some data are available on the mechanisms of tissue damage caused by CCl_4. The ATSDR Toxicological Profile for Carbon Tetrachloride (ATSDR 1989, Table 2–6) identifies several on-going mechanistic studies as well as one NIH-supported study focussing on the "Treatment/Antidote" of CCl_4 toxicity (J.A. Castro, Centro de Investigaciones Toxicologias, Buenos Aires).

Priority Recommendation: The identified data need is not considered

priority. These studies will become priority following the elucidation of mechanisms of toxicity and the evaluation of on-going studies.

IV. Summary: Prioritization of Data Needs for Carbon Tetrachloride

A. Exposure

Application of the hierarchy of research priorities presented in the Decision Guide begins with the evaluation of available analytical methods for carbon tetrachloride and proceeds through to assessing the need for epidemiologic studies. As stated previously, much information is available on carbon tetrachloride, albeit some of it from studies done quite some time ago. This does not mean that data derived from older studies are not adequate. ATSDR agrees with the National Research Council in that it is not appropriate to judge the quality of past and future studies solely by the standards of today.

Building a sound basic data foundation for higher level environmental research via the decision guide requires the determination of human exposure levels and media-specific data on CCl_4. Although referent tissue levels are currently being determined in on-going studies (NHANES III), no actual human exposure level data from individuals living near hazardous waste sites is anticipated to be collected. This information is necessary to assess the need to conduct human health studies of these populations and should be rigorously collected concurrently with the acquisition of data from the NHANES III study.

One effort is currently underway at ATSDR that will examine the extant data at the 134 NPL sites at which CCl_4 has been found. When complete, this database will include concentrations of CCl_4 in on-site and off-site media, the size of the potentially exposed population, and an indication of relevant routes of exposure. This database will be limited, however, in that it will contain only the site-specific information available to ATSDR via EPA documentation and the ATSDR Health Assessment. This database will be developed and evaluated before the need to collect additional media-specific data is assigned priority. This database will not, however, supply information on the levels of CCl_4 (or its metabolites) in the tissues of individuals living near hazardous waste sites or other exposed populations such as workers.

This information is necessary to establish a database that can be used to assess the need to conduct follow-up human health studies of populations exposed to CCl_4. In addition, carbon tetrachloride should be considered as a candidate for a registry of exposed persons as it has been found at a large number of hazardous waste sites in the United States. This recommendation will be provided to the ATSDR Division of Health Studies who will judge the extant information on CCl_4 against its criteria for initiating an exposure registry.

Thus, on the basis of the findings given in Section II and above, ATSDR is recommending the initiation of research or studies to fill the following exposure priority data needs (Table 3):

- Evaluation of existing data on concentrations of CCl_4 in contaminated environmental media at hazardous waste sites.
- Exposure levels in humans living near hazardous waste sites and other populations such as workers exposed to CCl_4.
- Candidate for registry of exposed persons.

B. Toxicity

In the case of CCl_4, much of the older toxicity data is quite acceptable, however, no studies have been performed on the immune system as a toxicologic endpoint via the most relevant route of exposure at waste sites, i.e. drinking water. Limited data suggest that parenteral exposure of animals to CCl_4 can affect the immune system (e.g., Tajima et al. 1985; Kaminski and Holsapple 1988), but these effects have generally not been investigated following oral, inhalation, or dermal exposure. The immune system has been determined recently to be a sensitive indicator of chronic toxicity for a variety of substances and as such should be evaluated for CCl_4 by the most commonly encountered route of exposure: oral (drinking water). In addition, data on chronic toxicity, and reproductive and nervous system toxicity, following exposure to CCl_4 via drinking water is limited and neither ATSDR MRLs or firm conclusions regarding the relevance of these endpoints can be drawn.

These two nonhuman research needs are justified because of the current widespread contamination of environmental media by carbon tetrachloride and the possibility that significant past exposures have occurred to a large population. Due to the obvious impact of reproductive/developmental effects, the possibility of the role of CCl_4 in causation must be evaluated. If the immune system is determined to be a sensitive indicator of carbon tetrachloride toxicity, immune "biomarker" evaluations could be utilized in human populations exposed to carbon tetrachloride.

As a consequence of the widespread medicinal, industrial and residential use of carbon tetrachloride, human exposure to this substance is occurring but there is only very limited epidemiological information concerning carbon tetrachloride. Thus, there are populations that exist that have experienced exposure to CCl_4 either via environment or occupation which should be identified to serve as a source of epidemiological data. Design of these studies should emphasize evaluation of systemic toxicity (including immunotoxicity and neurotoxicity), carcinogenicity, and reproductive toxicity.

Thus, on the basis of the findings given in Section II and above, ATSDR is recommending the initiation of research or studies to fill the following toxicity priority data needs (Table 3):

- Dose-response data in animals for chronic oral exposures; extended reproductive organ and nervous tissue (and demeanor) histopathological examinations should be included.
- Immunotoxicology testing via drinking water.
- Epidemiologic studies on the health effects of CCl_4

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TABLE 1.—CATEGORIES OF EXPOSURE DATA NEEDS

Category	Level I	Level II
Analytical	Methods for parent in REM.[1]	Methods for metabolites in REM.[1]
	Methods for parent in tissues.	Methods for metabolites in tissues.
Physical/chemical properties	Solubility, volatility, vapor pressure, Kow, Henry's law constant	
Exposure levels	Production, use release, disposal	Levels in REM [1], tissues.
Environmental fate	Anaerobic/aerobic	Small field plots.
	H_2O biodegradation Oxidation, hydrolysis, aerosolization, Photoreactivity, volatilization, soil adsorption/desorption	
Bioavailability		Food chain bioaccumulation, availability from REM.[1]

TABLE 1.—CATEGORIES OF EXPOSURE DATA NEEDS—Continued

Category	Level I	Level II
Level III exposure data needs:		
Exposure registries		
Human dosimetry studies		

[1] REM—Relevant Environmental Media

TABLE 2.—CATEGORIES OF TOXICITY DATA NEEDS

Category	Level I	Level II
Acute	Acute toxicity	
Repeated	Subchronic toxicity	Comparative toxicokinetics.
Chronic	Structure activity relationships (SAR)	Chronic toxicity.
Mutagenic	Ames, micronucleus	Additional genotoxicity studies.
Reproductive	Extended reproductive workup in subchronic	Multigeneration studies.
Developmental	*In vivo* screen, extended reproductive workup in subchronic.	2-Species developmental.
Immunotoxicity	Immunopathology in subchronic	Immunotoxicity battery.
Neurotoxicity	Neuropathology/demeanor in subchronic	Neurotoxicity battery.
Carcinogenic	Mutagenesis and subchronic results	2-year bioassay.
Level III toxicity data needs:		
Epidemiology		
Mechanistic studies		
Biomarkers		
Mitigation of toxicity		

TABLE 3.—ATSDR SUBSTANCE-SPECIFIC RESEARCH PROGRAM FOR CARBON TETRACHLORIDE

Category	Level I	Level II
Exposure data needs:		
Analytical	Standard, rapid method for biological tissues	
Physical/chemical properties		
Exposure levels		*EVALUATE EXISTING DATA ON LEVELS IN REM*; *LEVELS IN TISSUES*.
Environmental fate	Atmospheric lifetime, Flux rates from surface water	
Bioavailability		Bioavailability from REM.
Level III exposure data needs		
CANDIDATE FOR EXPOSURE REGISTRY		
Toxicity data needs:		
Acute		
Repeated	Dermal subchronic	Comparative toxicokinetics (Human metabolism).
Chronic		Inhalation, *ORAL*#, Dermal.
Mutagenic		
Reproductive		Multigeneration study (oral).
Developmental		Mammalian species (oral).
Immunotoxicity	*IMMUNOTOXICITY BATTERY (ORAL).*	
Neurotoxicity		Neurotoxicity battery (oral).
Carcinogenic		
Level III toxicity data needs:		
EPIDEMIOLOGY STUDIES ON HEALTH EFFECTS		
Mechanistic studies		
Biomarkers		
Mitigation of toxicity		

* UPPER CASE*: Priority data needs identified for carbon tetrachloride.
#: Should include extended reproductive & nervous tissue histopathological examination.

Dated: July 12, 1991.

Walter R. Dowdle,

Acting Administrator, Agency for Toxic Substances and Disease Registry.

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[6] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[7] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.